

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
Civil Action No. 83-2864(SA)

ANTONIO CIPOLLONE, individually,
and as Executor of the Estate
of Rose D. Cipollone,

Plaintiff,

-vs-

LIGGETT GROUP, INC., a
Delaware Corporation; PHILIP
MORRIS, INCORPORATED, a
Virginia Corporation; and
LOEW'S THEATRES, INC., a
New York Corporation,

Defendants.

TRANSCRIPT OF
PROCEEDINGS

Newark, New Jersey

May 2, 1983
MORNING SESSION

B E F O R E:

HONORABLE H. LEE SAROKIN
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

BUDD, LARNER, GROSS, PICILLO, ROSENBAUM,
GREENBERG & SADR, ESQS.,
BY: MARC S. EDELL, ESQ. & CYNTHIA WALTERS, ESQ.

-and-

WILENTZ, GOLDMAN & SPITZER, ESQS.,
BY: ALAN M. DARNELL, ESQ.,
Attorneys for the Plaintiff.

ARNOLD & PORTER, ESQS.,
BY: PETER K. BLEAKLEY, ESQ.,
BY: THOMAS E. SILFEN, ESQ.

Attorneys for the Defendant, Philip Morris.

Pursuant to Section 753 Title 28 United States Code,
the following transcript is certified to be an accurate
record as taken stenographically in the above-entitled
proceedings.

Phyllis T. Lewis, CSR
PHYLLIS T. LEWIS, C.S.R.

Official Court Reporter - United States District Court
P.O. Box 25588, Newark, New Jersey 07101

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PHYLLIS T. LEWIS, CSR, OFFICIAL COURT REPORTER, NEWARK, NJ

A P P E A R A N C E S: (Continued)

**GREENBAUM, ROWE, SMITH, RAVIN, DAVIS &
BERGSTEIN, ESQS.,**

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-and-

WEBSTER & SHEFFIELD, ESQS.,

BY: DONALD J. COHN, ESQ.,

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BY: WILLIAM S. TUCKER, JR., ESQ.,

-and-

SHOOK, HARDY & BACON, ESQS.,

BY: STEVEN PARRISH, ESQ.,

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Attorneys for Defendants,

Philip Morris and Lorillard.

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1 (May 2, 1988)

2 THE COURT: Good morning.

3 Please be seated.

4 Welcome back. I hope you all had a nice rest and
5 are all calmed down.

6 One thing I should say, apparently there was a
7 mixup. I was hoping that I could rule this morning on the
8 motion, but for some reason the briefs came in much later
9 than I thought, because I came back Thursday specifically to
10 work on it, but I hope that probably by tomorrow morning or
11 sometime tomorrow, I can have the motion decided. But I
12 need some more time because of the delay in the briefs. It
13 is nobody's fault, but it will take me another day or two to
14 have it accomplished.

15 Other than that, anything else before we bring in
16 the jury?

17 MR. EDELL: Your Honor, the other matter that we
18 discussed before we had our little interlude, the question
19 of the attorney/client privilege documents was the subject
20 of discussion, and the Court said you were going to locate
21 your papers on the matter. I don't know whether the Court
22 has. I don't --

23 THE COURT: I have found those papers but I have
24 not done anything with it, but I will get to it.

25 MR. EDELL: The Court has the transcript of the

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1 proceeding. I don't know whether you do or don't.

2 In addition we would also and I have written to Mr.
3 Kearney, we would like the Court to consider the redactions
4 made in Dr. Mold's diary by counsel for Liggett on the basis
5 of some attorney/client privilege.

6 Dr. Mold kept a diary, and what happened was when
7 the diaries were produced, counsel for Liggett came down and
8 covered up certain portions of the diary and we were given
9 copies of these -- of the entire diary with the redactions
10 made, based upon an asserted attorney/client privilege. I
11 would like the Court to consider those documents when you
12 rule on the motion.

13 I also asked Mr. Kearney to bring a copy of the
14 unredacted diaries with him today. I wrote a letter last
15 week and I don't know whether he has or has not responded.

16 THE COURT: What is the physical status of the
17 diary? Do I have them or will I have them?

18 MR. KEARNEY: That is why I did not bring them to
19 court today. I want to know what you want to do with them.

20 The physical status is this: At a deposition of
21 Dr. Mold which occurred in November of 1985, he produced I
22 believe it was 17 diaries.

23 From -- what we did, we had an opportunity to look
24 at them before the deposition and he, as you know, is a
25 former employee and we have put little pieces of paper over

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1 those sections of the diary that reflected attorney/client
2 communications. Based on our review of them, and in light
3 of this Court's determination and Judge Cowen's
4 determination earlier with respect to the privileged status
5 of Liggett's other documents, which is the documents you
6 have in your chambers, Liggett claimed privilege on 81
7 documents or so, and anyway at the deposition we agreed to
8 use the original there to question Dr. Mold on it and
9 reserve some other time for the presentation to the Court of
10 any challenge plaintiff may have with respect to the
11 assertion of the privilege in those documents.

12 I was of the view -- this was during the first
13 session of the discovery deposition of Dr. Mold, I was of
14 the view if taken care of at that time, if there was any
15 issue concerning the assertion of the privilege with regard
16 to those diaries it would be done then.

17 We adjourned the deposition, came back in December
18 for the final day.

19 Two years passed. '85 to December of '87,
20 beginning of '88. We took another deposition of Dr. Mold,
21 and the issue was still not raised by the plaintiff.

22 It is our position that he has delayed and that
23 were he to challenge those assertions of the attorney/client
24 privilege, it should have been done two years ago. What
25 we -- we did represent at the deposition that we would

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1 obtain the diaries in their complete form, copies of diaries
2 in their complete form so we have that. A box about that
3 big (indicating), and they are, as you can imagine, I guess
4 365 pages a year with certain portions of them usually like
5 a little -- in each year there may be anywhere from four,
6 five to assertions of privilege to 12 or 13.

7 It is our position it is too late. It is a
8 discovery matter, should have been brought to the magistrate
9 during discovery. But to do it now after the plaintiff's
10 case is in, in the middle of the trial puts an undue burden
11 on the Court, and it is really kind of silly, frankly, and
12 that is our position. It was never raised before.

13 THE COURT: Mr. Edell, what purpose would it serve
14 now?

15 Let us assume I or the magistrate reviewed the
16 entries and found that in some the attorney/client privilege
17 was improperly asserted. I assume we are talking about a
18 diary entry, not an underlying document. What would you do
19 with it?

20 You do not have Dr. Mold. You could not examine
21 him about it. What would we accomplish?

22 MR. EDELL: I would examine any witness they put
23 on, such as Dr. Kensler or Dr. Bryant, the entries in the
24 diary pertain to those people.

25 I could examine potentially some of the attorneys

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1 that were involved, you know. Mr. Kearney suggests that we
2 waived our right in some respect. The Court was clear on
3 Page 7 of your ruling back in September of 1985 when we
4 first brought the issue to the Court. You said, how will I
5 decide whether or not there should be an exception to the
6 attorney/client privilege?

7 We didn't make the assertion, your Honor, that this
8 was not an attorney/client privilege communication in the
9 Mold diaries.

10 What our position is now, what the Court said.
11 After the close of the plaintiff's case, I will decide
12 whether or not there was a prima facie case which would
13 warrant some type of a vitiation of the attorney/client
14 privilege. That is what the Court said. What purpose would
15 it have served for me to have brought in the diaries? We
16 would be in the same position we were then.

17 THE COURT: But even assuming that, suppose there
18 is a diary entry, meeting with attorney "X," what can I do
19 with that? Does it become admissible? Is it used by you
20 for discovery purposes?

21 MR. EDELL: I think it may be admissible. There
22 certainly, you know, it is a fine line that they are walking
23 here, Liggett. One instance, they cross-examine Dr. Mold
24 but then they assert the attorney/client privilege.

25 Now, statements made by Dr. Mold, are admissions of

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1 Liggett, if they were made in the course of his capacity as
2 assistant director of research and development, I think they
3 can come into evidence.

4 If there was a discussion, meeting with Joe Greer
5 concerning dissemination of information on palladium
6 cigarettes, Greer advises cannot go to Cold Spring Harbor
7 because it would be admission against interest, why would
8 that not come in as an admission against Liggett --

9 THE COURT: Of course, I guess I am assuming that
10 diaries' calendars do not contain that much --

11 MR. EDELL: They do. These are very detailed
12 diaries in many instances.

13 THE COURT: I think in the first instance I ought
14 to glance at them and see what is involved. You say you
15 have them or can produce them and whether I do it or turn it
16 over to the magistrate -- how many pages are we talking
17 about?

18 MR. KEARNEY: Talking about a box full of documents
19 of diaries. I can't tell you how many pages you have to
20 look at. I would submit whoever does it, has to look at the
21 diaries entries around the place where the assertion
22 privilege was made to put it in context.

23 Let me say, Dr. Mold testified on his video tape
24 about what Greer told him with respect to Cold Spring
25 Harbor. That is why he was crossed on it.

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1 Another point is that this is not the same
2 situation as you have with respect to the ruling you made in
3 September of 1985. There, Judge, I submit that Mr. Edell
4 did what I thought he should right properly have done if he
5 had a claim he wanted to assert with regard to this
6 attorney/client privilege claim.

7 What he did, he brought it to Judge Cowen, claimed
8 all of our assertions were improper. Judge Cowen ruled they
9 were covered by the attorney/client privilege.

10 He appealed it to you in September of '85. You
11 concurred in that but then you said you would like to
12 further think about it. Also said, if the exception
13 applied, at some later date you would consider it.

14 The point is here with regard to these assertions
15 the first step was never made. Nobody reviewed them for the
16 attorney/client privilege or its propriety at all.

17 What Mr. Edell is saying now, I gather, is that he
18 is skipping that step and asserting that the exception
19 applied to all of it.

20 As I say, I don't know how it should be done and I
21 don't know whether or not just looking at these would be
22 very useful for you. We have to have an opportunity as we
23 said to you in September of '85 to put them into context to
24 make our assertion --

25 THE COURT: The only reason now I want to look at

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1 them is not to make any rulings but to see what is involved,
2 and then before I do anything further on it, I will let you
3 know what the proper procedure ought to be.

4 What I would like first is somebody to deliver some
5 of them to chambers, so I can get an idea of what they look
6 like and how many redactions there are and then we will talk
7 about it some more.

8 MR. KEARNEY: I would submit what we have to do is
9 go back to the first step which should have been done in
10 '85, '86 or '87, which is to permit an opportunity to
11 demonstrate the assertion, the propriety of the assertion of
12 the privilege in each and every instance and as we were
13 upheld in --

14 THE COURT: That may have to be done but let me
15 look at them. Give me the samples.

16 MR. EDELL: There are I believe two documents which
17 fall within the same argument that we asked for Philip
18 Morris to produce. I don't know whether they have submitted
19 it or intend to submit it to the Court for in-camera
20 submission.

21 MR. PARRISH: We have.

22 THE COURT: You have?

23 MR. PARRISH: Two documents Ms. Walters requested
24 and I brought them today.

25 MR. BLEAKLEY: I have not had an opportunity to

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1 look at them, and I want to look at the documents that are
2 relevant to the two documents that Ms. Walters asked for
3 before we state our position.

4 THE COURT: Do I have the documents?

5 MR. BLEAKLEY: You do not have them and I think
6 this doesn't have to be done today and I think I ought to
7 have an opportunity to review these and the surrounding
8 documents.

9 THE COURT: Bring in the jury.

10 MR. BLEAKLEY: One other issue. Since we have been
11 away for a week, there was a fair amount of publicity over
12 the weekend after the last hearing on Friday on the mistrial
13 and the like, I would like to suggest that your Honor ask
14 the jury, not individually polling, but ask the jurors
15 whether or not they have seen any publicity or were exposed
16 in any way, sort of a general question, see whether or not
17 any of them might have seen any publicity, particularly
18 appearing over last weekend.

19 There was an editorial in the Bergen Record on
20 Sunday April 24th, and there were a number of articles in
21 the papers all over New Jersey and New York.

22 THE COURT: All right. Any objection to that Mr.
23 Edell?

24 MR. EDELL: Are we going to do this every day,
25 every time there is a weekend?

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1 MR. BLEAKLEY: If necessary, your Honor, yes.

2 MR. EDELL: I don't see any purpose in it, your
3 Honor.

4 THE COURT: Let me suggest this as a compromise,
5 Mr. Bleakley. At the end of the day, as I usually do, I
6 will give the jury an instruction and tell them that they
7 are obligated to report to me if anything has come to their
8 attention. Is that satisfactory to you?

9 MR. BLEAKLEY: Not as satisfactory as asking them
10 this morning which would be directed at what might have
11 occurred during the past week.

12 My preference would be to ask the jurors when they
13 come in this morning if during the nine days we have had
14 off, they have been exposed in any way to the publicity
15 about the case.

16 THE COURT: Well, I think I will follow the
17 suggestion I made. I will do it at the end of the day, not
18 to over-emphasize it, but instruct the jury if they have,
19 they should report it to me.

20 Bring the jury in.

21 THE CLERK: All rise.

22 (Jury present.)

23 THE COURT: Good morning.

24 Be seated.

25 Hope you had a pleasant week off and are fresh and

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1 alert.

2 MR. COHN: Dr. Irwin Miller, your Honor.

3 THE COURT: All right.

4 THE CLERK: Put your left hand on the Bible raise
5 your right hand.

6
7 I R W I N M I L L E R, having been duly sworn,
8 testified as follows:

9 THE CLERK: Please be seated.

10 State your name and spell your name for the record.

11 THE WITNESS: Irwin Miller, spelled M-i-l-l-e-r.

12 MR. COHN: Your Honor, I forgot to hand out jury
13 binders for Dr. Miller.

14 THE COURT: Mr. Underwood?

15 Can I see counsel at side bar?

16 (The following takes place at side bar.)

17 THE COURT: I suppose I should have asked before,
18 but are any of the witnesses within the next two days going
19 to talk about the palladium cigarette?

20 MR. COHN: The next --

21 MR. BLEAKLEY: Not the next two. We changed our
22 order in order to give a little leeway.

23 THE COURT: I would like to have a chance to rule
24 on it before that.

25 MR. BLEAKLEY: The third witness this week begins

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1 on the subject.

2 MR. COHN: We had maybe --

3 THE COURT: I hope to have a decision tomorrow or
4 early Wednesday.

5 MR. COHN: Next two witnesses don't. However long
6 they may take, I don't know.

7 THE COURT: Fine.

8 (End of side bar.)

9 DIRECT EXAMINATION

10 BY MR. COHN:

11 Q Dr. Miller, where do you live?

12 A I live in [DELETED]

13 Q What is your present occupation?

14 A Director of statistical analysis for the Raytheon
15 Company.

16 Q Are you a statistician?

17 A Yes.

18 Q Tell the Court and jury what that is, please.

19 A A statistician is a scientist who uses theories of
20 mathematics and probability to analyze data and to determine
21 how data analysis relates to the drawing of conclusions.

22 Q Could you tell the Court and jury your educational
23 background?

24 A Yes.

25 I have a bachelors degree in mathematics from

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1 Alfred University, received it in 1950. Master's degree in
2 mathematics from the statistics area of concentration from
3 Purdue University in 1952, and in 1956 I received the Ph.D
4 degree in statistics from Virginia Polytech Institute.

5 Q And you received your Ph.D in 1956?

6 A Yes.

7 Q Between the time you got your Master's degree and the
8 time that you got your Ph.D, what did you do?

9 A Well, about a year after I received my Master's degree I
10 was inducted into the United States Army, during the Korean
11 War, and I was assigned to Redstone Arsenal in Alabama,
12 where I was assigned as the chief statistician for the
13 guided missile development reliability office.

14 Q When you got out of the army, you went back to get your
15 Ph.D?

16 A That is when I went to Virginia Tech and received my
17 Ph.D a year and a half later.

18 Q And, Dr. Miller, could you give the Court and jury a
19 brief description of what you have done since you got your
20 doctorate?

21 A Well, after I received my doctorate, I took a position
22 with United States Steel Corporation, now called USX, their
23 applied research laboratories in Monroeville, Pennsylvania.

24 My position there was the head statistician of the
25 applied mathematics section, which gave support,

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1 consultation data analysis, experimental design for the
2 metallurgists, scientists who were doing research in steel
3 and other metals.

4 Q Tell the jury what you did from then on.

5 A After that, I moved to Arizona and assumed the position
6 initially as associate professor of mathematics at Arizona
7 State University, where I taught mathematics and statistics
8 and had a considerable amount of experience in consulting
9 with a number of different companies as a statistician.

10 When I left Arizona State University in early 1965
11 I was professor of statistics and director of the
12 statistical laboratory.

13 On February 1st, 1965 I joined the firm of Arthur
14 D. Little as a senior member of the professional staff, as a
15 consultant in the field of statistics.

16 Q When you joined Arthur D. Little in 1965, Dr. Miller,
17 could you tell the jury generally what Arthur D. Little was
18 and what it did?

19 A Arthur D. Little is an international firm that does
20 consulting and contract research in a wide variety of areas
21 that has a large staff of experts and professionals in many,
22 many different sciences and disciplines.

23 I have often said my university would have been
24 proud to have a faculty of such power.

25 And I was one of the members of that consulting

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1 staff, concentrating in the area of statistics.

2 Q And this was in 1965?

3 A Starting in early 1965.

4 Q What did you do thereafter?

5 A I remained with Arthur D. Little. In 196 -- early 1969
6 a section called behavioral sciences and statistics was
7 formed in one of the divisions, the one to which I belonged.
8 I was asked to manage that section.

9 Late 1969 I took a leave of absence and went to
10 Wesleyan University and assumed the position of director of
11 academic computer center and adjunct professor of
12 mathematics, so I oversaw the activity of the computer
13 center and taught a couple of courses in actually
14 statistics, returning to Arthur D. Little in the spring of
15 1971.

16 At that time --

17 Q Just to stop you there, Dr. Miller, had you had any
18 other academic posts besides teaching up through 1969?

19 A Yes. In -- at the time I was at United States Steel, I
20 taught at what was then known as Carnegie Tech-- no,
21 Carnegie-Mellon University. I taught statistics in an
22 evening course.

23 And then for a couple of years, between '67 and
24 '69, I was an adjunct professor of statistics in the
25 graduate school of business administration at Boston

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1 University, teaching evenings.

2 Q So then you went to Wesleyan from '69 to '71 and back to
3 Arthur D. Little in '71?

4 A Correct.

5 Q Could you continue please with what your professional
6 experience has been?

7 A Yes.

8 In 1973 -- first I should say that when I returned
9 to Arthur D. Little in '71, I was a member of the staff of
10 the division to which I had belonged earlier. They have an
11 a division staff of senior consultants.

12 Shortly thereafter I formed a new statistics
13 section, which I managed until 1975.

14 During that period in 1973 I was elected
15 vice-president of Arthur D. Little. My official title was
16 vice president for statistics.

17 In 1975 I was asked to head a team to look into the
18 possibility of acquisition of a survey research company.
19 And in August 1975, under my guidance and direction, Arthur
20 D. Little purchased Opinion Research Corporation, located in
21 Princeton, New Jersey, from McGraw-Hill.

22 At that time I was asked to temporarily assume the
23 management of the company until we could find, hire from
24 outside, somebody to take over the position, so I spent
25 about ten months in Princeton managing Opinion Research

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1 Corporation.

2 Q What was the business of Opinion Research Corporation?

3 A Opinion Research Corporation, or may I call it ORC, is a
4 survey research company. One of the larger, older companies
5 in its field, and it performs surveys in a wide variety of
6 applications.

7 Q And you say you were -- you took over the duties as
8 president until you were able to hire somebody to take that
9 job?

10 A Correct.

11 Q And that took about ten months?

12 A Approximately ten months before we could hire and get
13 that person set up and in the job.

14 Q Then what?

15 A Then I returned to Cambridge, Massachusetts, which is
16 the headquarters of Arthur D. Little, where I was asked to
17 supervise Opinion Research Corporation, the statistics
18 section, which I had headed before moving down to Princeton
19 on a temporary basis and the three sections then comprising
20 the biology division of Arthur D. Little.

21 Q And how long did you remain in that position?

22 A Remained in that position until late 1980.

23 At that time we were having some problems with the
24 management of ORC, and I was asked to move this time on a
25 more permanent basis to Princeton, so I relocated my

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1 residence to Princeton and assumed the position of chairman
2 and chief-executive officer of Opinion Research Organization
3 on a permanent, full time basis.

4 Q How long did you remain in that job?

5 A Remained in that position until September 1, 1986. At
6 which time I took retirement from both ORC and Arthur D.
7 Little.

8 Q Now, during the time that you were president of Opinion
9 Research Corporation, from 1980 to 1986, could you give the
10 Court and jury some idea what you did as president and the
11 kind of work you were involved in?

12 A Certainly.

13 I really was involved in two areas. First, of
14 course, general management and administration. I was
15 concerned with all of the things that a chief executive
16 officer is concerned about; personnel, business, the quality
17 of the work, so forth.

18 Also as the senior statistician in residence at the
19 company, I found myself giving advice to the survey
20 researcher on sample design, on analysis of the data of
21 surveys and the like.

22 I also reviewed a large number of questionnaires
23 because in the survey research business one must be careful
24 that they are adequate and proper questionnaires for the
25 purpose they are intended for.

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1 Q How many surveys did Opinion Research do a year while
2 you were president?

3 A On the average during that period it was between three
4 and 400 surveys a year.

5 Q And could you just tell the jury how a survey would be
6 conducted?

7 A Yes, the process is generally the same as what I am
8 about to describe, only divides in details depending upon
9 the specific nature of the survey.

10 Every survey starts out with identification of some
11 population, that is, group of individuals or household or
12 what-have-you, and then the proscription of how to take a
13 sample, so sample design is the first step.

14 Then instrument design. The instrument is often in
15 the form of a written questionnaire but need not be, could
16 be a discussion outline if, for example, the interview will
17 be a group interview or general discussion. The instrument
18 is designed, reviewed and prepared for use.

19 The next step is to administer the instrument, that
20 is, do the interviews, and there are many different ways
21 they interview. They interview in the home. They interview
22 in the office. Sometimes the interviewer fills out the
23 questionnaire and sometimes the respondent, that is the
24 person being interviewed, fills out the questionnaire.

25 Sometimes it is a shopping mall intercept. I

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1 imagine most of us have been stopped in a shopping mall and
2 asked a few questions. That is part of the process. Maybe
3 a telephone interview. We had our own telephone
4 interviewing on-site and managed those ourselves.

5 Following the interviews the data have to be
6 returned to the central headquarters, checked to make sure
7 they are complete, accurate and recorded. The general
8 method to record the data is to put it in a form that can be
9 read by a computer, either punch cards or computer tapes or
10 some format so further data processing can be performed
11 automatically on today's modern, high speed computers.

12 The next process is finally to perform certain
13 analysis at the request of the person who is directing the
14 survey to make sure that the analyses are performed, that
15 that person has the summarized and analyzed information
16 necessary for him or her to prepare a report, a written
17 report which goes to the client that describes the results
18 of the survey. That, after all, is what the client is
19 paying for.

20 Q Thank you, Doctor.

21 After you retired from ORC and Arthur D. Little,
22 what did you do?

23 A At that point I took the position at Alfred University
24 as professor of mathematics. Alfred University is a little
25 town in western New York State.

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1 Q From there you went to your present position?

2 A Yes. On June 1st, '87 I took this position at Raytheon
3 Company.

4 Q Dr. Miller, have you written any books or scientific
5 articles that have been published?

6 MR. COHN: Your Honor, if the jury can refer to it.

7 THE COURT: The jury may turn.

8 A I have written several books in statistics and
9 mathematics and published perhaps ten or a dozen articles in
10 journals.

11 Q They are listed on your curriculum vitae?

12 A Yes, the ones listed here.

13 Q Now, do any of these articles have anything to do with
14 cancer or statistical analysis of any research dealing with
15 cancer?

16 A Yes.

17 I believe it is the last four on the list. All of
18 these were prepared in one way or another in connection with
19 a research contract that I had when I was at Arthur D.
20 Little. The client in that case was the National Cancer
21 Institute and I was assisting them by providing general
22 counseling and consulting on the statistics related to the
23 experimental work that they were doing in the development of
24 anti-cancer compounds.

25 Q Now, over the course of your work as a statistician,

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1 have you had the occasion to read the literature with
2 respect to epidemiological studies concerning smoking and
3 lung cancer?

4 A Yes, I have.

5 Q Tell the Court and jury what you have done in that
6 regard.

7 A Yes.

8 In the mid to late 60's, I headed up the team of
9 consultants at Arthur D. Little that was preparing abstracts
10 and commentaries on the references that were contained in
11 the 1967, I believe it was Surgeon General's Report. And I
12 have followed up, not on all, but on some reasonable portion
13 of the epidemiological literature in this field since then.

14 Q Now, have you, at our request, performed statistical
15 analysis with respect to the data derived from the American
16 Cancer Society 25 State study?

17 A Yes, I have.

18 Q And could you tell the Court and jury briefly what data
19 you looked at and generally what you did?

20 A Yes. I will be pleased to.

21 The data were presented to me in the form of a
22 computer tape.

23 Q How did you get the data?

24 A The data were provided by counsel. I understand that
25 they received copies of the original tapes that the American

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1 Cancer Society prepared from their survey through the
2 discovery process for this case, and these copies were
3 provided to me by counsel.

4 Q Okay.

5 And could you tell the Court and jury what kinds of
6 analysis that you have done with respect to these?

7 A Yes.

8 Once everything verified that the data on the tapes
9 was representative or accurately recorded what was in their
10 questionnaires, I then performed multiple regression
11 analysis on these data for the purpose of determining what
12 are the joint relationships, joint correlations among the
13 many, many factors and variables that information was
14 gathered on by the American Cancer Society.

15 MR. COHN: Your Honor, I tender Dr. Miller as an
16 expert statistician with particular reference to statistical
17 methods of survey research and the analysis interpretation
18 of data derived from such surveys including the
19 epidemiologic studies of smoking and lung cancer.

20 THE COURT: Any voir dire or objection?

21 MR. EDELL: Yes, your Honor.

22
23 VOIR DIRE EXAMINATION:

24 BY MR. EDELL:

25 Q Dr. Miller, you are not a biostatistician, are you?

P1T 003895

1 A I have done a lot of work in the area of biostatistics.
2 I don't think I could, not -- no, I am not a
3 biostatistician. I am a general statistician who applied
4 statistical methodology in a wide variety of fields
5 including biostatistics.

6 Q Remember my asking you at your deposition page 94 line
7 8: Do you consider yourself to be a biostatistician?

8 Answer: I worked in that field but I consider
9 myself to be a generalist whose strengths are in the area of
10 statistical methodology.

11 Remember that?

12 A Yes, I do.

13 Q And you are not an epidemiologist, are you?

14 A I am not an epidemiologist in the sense that I've
15 devoted my life to the practice of epidemiology, but
16 epidemiology is survey research and I am a survey
17 researcher.

18 Q Doctor, epidemiology differs significantly from the work
19 of a statistician, isn't that correct?

20 A No, sir, I don't believe it is correct.

21 Q Isn't it a fact that the difference between you and the
22 epidemiologist is that an epidemiologist is concerned with
23 the study of human populations as they relate to disease.
24 Isn't that correct?

25 A I think there are two parts to the question.

P1T 003896

1 Yes, an epidemiologist is concerned with the study
2 of human populations as they relate to disease. I agree.
3 But I would not characterize that as a difference between
4 what I do and an epidemiologist does because, for the most
5 part, these are all based upon statistical theories and
6 statistical methods which I have studied and applied in a
7 wide variety of areas.

8 Q Doctor, you testified in this case on behalf of Liggett
9 & Myers --

10 A Yes.

11 Q -- as a statistician. Matter of fact, Mr. Cohn was the
12 same person asking you questions in that case?

13 A Correct.

14 Q Remember being asked this question page 1211:

15 Question: You are not an epidemiologist?

16 Answer: I am a statistician.

17 Question: What is the difference between you and
18 an epidemiologist?

19 Answer: An epidemiologist is particularly
20 concerned with the study of human populations as they relate
21 to disease.

22 Remember those questions and answers?

23 A I don't remember them except from what you said because
24 that was some years ago, but it is perfectly consistent with
25 what I am saying now.

P1T 003897

1 Q Do you remember these questions and answers? Did I read
2 it correctly?

3 A Yes. You have read correctly from the transcript.

4 Q And an epidemiologist is someone who spent a substantial
5 portion of their professional life looking into the question
6 of causation or association between various factors and
7 disease in human beings. Correct?

8 A Partially correct, because I don't believe epidemiology
9 can deal with questions of causation. But can deal with
10 questions of associations.

11 Q You never taught a course in epidemiology?

12 A Not with that title.

13 Q Never conducted an epidemiological study?

14 A Conducted an analysis but not the full study.

15 Q Simple question: Have you ever performed an
16 epidemiological study, yes or no?

17 A The answer was the same, in part yes but not in toto.

18 Q Did you perform a study, actually design a study, design
19 the questionnaire, figure out how the question should be
20 asked, to whom they should be addressed, ever do it?

21 A With respect to generally or with respect to
22 epidemiology?

23 Q Epidemiology.

24 A No.

25 Q In epidemiology have you ever written a paper on

P1T 003898

1 cigarette smoking and health?

2 A No. Not per se on cigarette smoking and health.

3 Q Cigarette smoking and lung cancer. Never published a
4 paper on it?

5 A No.

6 Q Never published a paper on cigarette smoking and heart
7 disease, have you?

8 A No.

9 Q And you don't know anything about the causes of lung
10 cancer, isn't that correct?

11 A Correct. I don't know if anybody else does either.

12 Q And you have no opinion as to whether or not anything
13 causes lung cancer. Isn't that correct?

14 A I don't know.

15 MR. COHN: Objection. This is not voir dire.

16 MR. EDELL: I think it is. I think it is based
17 upon some of the statements contained in the expert's report
18 and all germane to whether or not he would be entitled to
19 testify pursuant to the report.

20 THE COURT: Let me hear the last question.

21 (The requested portion was read back by the
22 reporter.)

23 Sustained the objection to that, does not go to the
24 qualifications.

25 Q Have you participated in any epidemiological study, sir,

P1T 003899

1 which concerned the determination of the health consequences
2 of cigarette smoking?

3 A If by "participated," you mean to include, have I
4 performed analysis on the data of such studies, the answer
5 is, yes.

6 Q You did it in this case?

7 A Did it with respect to the American Cancer Society
8 study.

9 Q In this case?

10 A I am not sure I know what you mean.

11 Q You did it after you were hired by Mr. Cohn to do it
12 with regard to cigarette litigation?

13 A That is the correct point in time, I have been wanting
14 to do it for many years.

15 Q But you never did it in your capacity as a professional
16 statistician where you actually participated in an
17 epidemiological study like many biostatisticians or
18 epidemiologists have?

19 MR. COHN: Objection to the form of the question.

20 THE COURT: Overruled. If he can answer it.

21 Can you answer it in its present form?

22 THE WITNESS: I can try. Not sure I can because
23 you have lumped, sir, biostatistician and epidemiologists.

24 THE COURT: Break it up.

25 Q What is a biostatistician?

P1T 003900

1 A That is a statistician first who happens to apply
2 statistical methods to investigations in biology, not
3 necessarily and sometimes rarely to epidemiology.

4 There is some overlap between biostatistics and
5 epidemiology. These are both fields of applications of
6 statistics. I distinguish between a biostatistician and
7 epidemiologist in terms of field of application, not in
8 terms of general knowledge or theory.

9 Q There are biostatisticians who have participated in
10 epidemiologic studies to look into the health consequences
11 of cigarette smoking, are there not?

12 A Yes.

13 Q And there are epidemiologists who have done the same
14 thing?

15 A Yes.

16 Q You have never done that outside of the scope of the
17 work that you did for Mr. Cohn's firm in these cigarette
18 litigation cases?

19 A By "that" --

20 Q By looking into the epidemiologic, performing or
21 participating in an epidemiologic study to determine the
22 health sequences of cigarette smoking?

23 A I can only remind you I participated in the study to the
24 extent I analysed the data that came out of it.

25 Q But that was in the context of your appearing as an

P1T 003901

1 expert witness, doing work in the context of cigarette
2 litigation?

3 A It was only this case that gave me the opportunity to
4 receive that data, data which I requested many years ago for
5 just this purpose and could not receive it because it was
6 denied.

7 Q It is a simple question. You received --

8 MR. PARRISH: I don't like his clarification of
9 whether it is a simple or not.

10 MR. EDELL: I am trying to formulate a simple
11 question and I will try again.

12 Q The work that you did analyzing epidemiological
13 information on cigarette smoking and the health consequences
14 of cigarette smoking was done as a result of your being
15 retained by Mr. Cohn's firm in regard to cigarette
16 litigation, is that correct or not?

17 A Yes. I have already testified to that fact.

18 Q None of the books that you have written concern
19 epidemiology, do they?

20 A Not specifically.

21 Q The books that you have written are, for example,
22 Probability and Statistics for Engineers?

23 A Correct.

24 Q In your curriculum vitae?

25 A Yes.

P1T 003902

1 Q Manual of Experimental Statistics?

2 A Correct.

3 Q And there are people who are epidemiologists and
4 biostatisticians who have written books in the area of
5 epidemiology and its relationship to the health consequences
6 of cigarette smoking?

7 A Yes. There are books on epidemiology. I am not sure
8 about the latter part.

9 Q And the survey work you were talking about before, that
10 was opinion research survey. Is that correct?

11 A If you mean -- again, forgive me.

12 Q OCR?

13 A ORC.

14 Q Sorry.

15 A If you mean surveys conducted by opinion research as a
16 company, yes. If you mean, they were surveys that were
17 restricted to the area of research and opinions, then the
18 answer would be no.

19 Q They were not epidemiologic studies?

20 A Not per se although there were a number of studies in
21 the general health area.

22 Q They were not epidemiological?

23 A Not as formally defined.

24 Q Not as you would define them?

25 A No.

P1T 003903

1 Q And you have done statistical analysis in banking,
2 rocket engineering. Tell us the other areas.

3 A As I mentioned before, I did a great deal of statistical
4 analysis on behalf of the National Cancer Institute in their
5 experimental program to find drugs to use against cancer.
6 Done statistical analysis of survey data, in a wide variety
7 of surveys more numerous than I could mention.

8 Q The survey for the American Cancer Society -- for the
9 National Institute for Health or?

10 A National Cancer Institute which is, as you must know,
11 part of the National Institute of Health.

12 Q That was not an epidemiological study, was it? It was a
13 study of mice?

14 A I don't think I would characterize it that way and it
15 was not a single study.

16 It was an association with the doctors and the
17 pharmacologists and the toxicologists who worked for the
18 Cancer Institute to provide them ongoing and constant advice
19 on the statistical methods of analysis and the statistical
20 aspects of all of the work that they were doing. It was not
21 a single study.

22 Q It was an animal study?

23 A Animal studies but the last two papers in my curriculum
24 vitae describe work I did in correlating these studies with
25 human clinical studies in cancer.

P1T 003904

1 Q And the work that you performed in 1969 surveying
2 epidemiological literature that was done -- let me make sure
3 we are looking at the same document.

4 The summary of Basic Citations in the 1968
5 Supplement to the Public Health Service Review?

6 A That is the title.

7 Q This was a report to the law firm of Shook, Hardy,
8 Ottman, Mitchell & Bacon, not a scientific review but for
9 lawyers?

10 A I don't think I would say just because it was a report
11 to lawyers that it couldn't possibly be a scientific review.

12 In fact, we were asked to conduct an unbiased
13 scientific assessment of the papers, that is what we did.

14 Q Read to the jury, sir, where it says "report."

15 A Yes. It is and as I testified a moment ago a report to
16 Shook, Hardy, Ottman, Mitchell and Bacon, but you made a
17 distinction because it is a report to lawyers, it can't be
18 scientific, and that is the distinction I could not agree
19 with making.

20 MR. EDELL: No other questions on voir dire.

21 I would like to be heard on the extent of his
22 testimony.

23 (The following takes place at side bar.)

24 MR. EDELL: Have you furnished the Judge with a
25 copy of the witnesses' report?

P1T 003905

1 MR. COHN: I don't think we did.

2 MR. EDELL: That is how we were planning to do it.
3 Do you have an extra copy?

4 THE COURT: Somebody has.

5 MR. DECKER: I have here as identified there are
6 two reports.

7 MR. EDELL: This witness, you will see, has been
8 offered to testify with regard to the issue of causation,
9 epidemiologic studies cannot prove causation. He has no
10 qualifications in that regard. He is a statistician, not an
11 epidemiologist, not a biostatistician. The work he has done
12 in this area is evaluating reports for lawyers, from his own
13 admission.

14 He is a statistician which makes him capable of
15 looking at data to see if there are any statistical errors,
16 but in terms of his abilities to determine whether or not
17 his efforts are sufficient to conclude the question of
18 causation when he has no training in the area of causation,
19 no expertise in the area. Never conducted any
20 epidemiological studies, never written on it. Where he has
21 done a variety of statistical things, none of which have to
22 do with the question of cigarette smoking or causation or
23 any other disease, doesn't place him in the position to
24 testify as to whether or not information is sufficient or
25 insufficient from which one can conclude that the question

P1T 003906

1 of causation has been resolved or hasn't been, or what
2 variables, what other factors should be taken into
3 consideration when determining whether or not cigarette
4 smoking does or does not cause lung cancer.

5 He has performed what he described as a regression
6 analysis, and he includes, based upon his own judgment, some
7 350 to 500 variables that he says are relevant in seeing
8 how -- what the real relationship is between cigarette
9 smoking and lung cancer.

10 I don't know what in his qualifications has come
11 out that so far permits him to make, one, a judgment as to
12 what variables should be included. Two, what the
13 significance of any of the computations are to the issue of
14 causation.

15 THE COURT: Mr. Cohn?

16 MR. COHN: Well, Dr. Miller is qualified as a
17 statistician to know -- to apply statistical methods to
18 data. That is what he will do.

19 He will testify about his opinions having applied
20 standard statistical methods of analysis to this large body
21 of data, which was collected by the American Cancer Society
22 and which we finally were able to get through discovery.

23 The data was collected by the American Cancer
24 Society to the extent that there are many factors and
25 variables in that data it is there.

P1T 003907

1 One of the reasons Dr. Miller wanted to analyze
2 this data back in '67, because it was the greatest
3 repository of data. Whatever its shortcoming, it was the
4 best. Well, he finally had access and did a standard
5 statistical method of analysis on these factors. He did not
6 choose them, they were in the questionnaire.

7 THE COURT: Was he going to give an opinion as to
8 causation?

9 MR. COHN: He will testify that given his review of
10 the epidemiological data, and given his review and analysis
11 of the American Cancer Society data, it is inconsistent with
12 the hypothesis that smoking causes lung cancer. He will
13 testify as a statistician who, as a regular part of his
14 work, tests hypothesis against --

15 MR. EDELL: Your Honor, the variables were included
16 by him. I can show you in his deposition where he says it
17 was his judgment as to what variables he wanted to include.

18 MR. COHN: This goes to the weight.

19 THE COURT: You said the variables came from the
20 American Cancer Society?

21 MR. COHN: I said factors and variables. We will
22 go into it at great length and I tried to be specific but
23 the point is, that the data is from the American Cancer
24 Society, he will explain to the Court and jury what he did
25 with it --

P1T 003908

1 THE COURT: What I will do --

2 MR. EDELL: That is a big difference.

3 MR. COHN: Is not.

4 MR. EDELL: Let me finish.

5 We are not taking the situation where he has 50
6 variables which were the same 50 used in the analysis
7 performed by the American Cancer Society and he is doing
8 another computer program on it with the variables and
9 telling what the correlations are, whether the statistics
10 come out the same. He has decided to include 350
11 independent variables -- independent variables, sorry, of
12 his own choosing that were not used in the American Cancer
13 Society.

14 THE COURT: Give me an example of what --

15 MR. EDELL: A person's weight is missing on a
16 questionnaire. He decided to include it as a variable in
17 his analysis. Such as whether or not a person, a woman had
18 a vaginal discharge, whether or not her nipples were sore.
19 I can go on and on and on with the list of things. I mean
20 it goes on, Judge.

21 THE COURT: Let us take those as the examples, the
22 ones he gave.

23 How does this witness deal with those variables as
24 a statistician?

25 MR. COHN: There are data which he runs the

P1T 003909

1 multiple analysis on, okay. To the extent that the data
2 shows that the -- this is all done through computer programs
3 with statistical analysis. Not done on just that I decided
4 on this, he starts with all of the rungs, the regression
5 analysis, to the extent things are not related, they kind of
6 get kicked out.

7 THE COURT: Does he make a judgment as to the
8 significance of the variables?

9 MR. COHN: He starts with all the data which he got
10 from the American Cancer Society. He did not decide what is
11 in the data. The whole point we are trying to make is, you
12 can't tell what is related and what is associated, can you
13 do this kind of a regression analysis because the data is
14 there, because the American Cancer Society asked the
15 question, they must have thought there was some reason for
16 getting the data.

17 THE COURT: Going to have him go through that
18 before his opinion?

19 MR. COHN: Yes.

20 THE COURT: I can't deal with it in a vacuum.
21 Before he is asked any opinion questions I want him to go
22 through how he arrived at this opinion, and then I will give
23 you a further opportunity to be heard, because Mr. Cohn has
24 said initially that the variables are exactly as they come
25 out of the American Cancer Society. You said that that

P1T 003910

1 isn't correct --

2 MR. COHN: I said he started with all the factors
3 in the data, and he started to do regression analysis, and
4 computer printouts which were not -- Mr. Edell would suggest
5 that he made an independent judgment as to what to include
6 or not to include, and that is where we part company.

7 MR. EDELL: Question: Are there standard criteria
8 that you use in order to come up with the created variables?

9 Answer: They are called education, experience and
10 common sense, so you have to exercise your individual
11 judgment.

12 He decided himself.

13 MR. COHN: Talking about different things.

14 MR. EDELL: No.

15 THE COURT: Let us follow my suggestion. There are
16 to be no ultimate opinion questions asked of the witness
17 until I understand the basis for his opinion.

18 MR. EDELL: Will he be permitted to say the reason
19 this is important to be included?

20 THE COURT: That is a matter of opinion.

21 MR. COHN: I didn't hear Mr. Edell.

22 MR. EDELL: I don't want him to say the reason it
23 is important to include this is because you're confounding
24 and when you are trying to find out --

25 MR. COHN: Let me say, I am going to ask the

P1T 003911

1 witness did he conduct relative risk, use two factors, maybe
2 three, can a relative risk ratio express more than that?
3 No. How do you do that? Multiple regression analysis, does
4 that take into effect other factors?

5 THE COURT: But the ground rules are that he is not
6 to be asked any opinion questions as to the significance of
7 anything or any ultimate opinion until I see the basis for
8 it.

9 I understand Mr. Edell's objection and position.

10 MR. COHN: When he is starting to talk about what
11 he did, he obviously is giving his opinion as a statistician
12 as to this is the appropriate way to analyse the data. I
13 think he is perfectly entitled.

14 THE COURT: If it's based upon statistics we have
15 no problems.

16 MR. EDELL: Your Honor, the problem that we have is
17 that he exercised his own judgment in deciding which
18 variables to include, and I don't think there is any dispute
19 as to which variables to include in the regression analysis.

20 Now, I don't think he is qualified to do that.

21 THE COURT: Do you concede it?

22 MR. DECKER: No.

23 MR. EDELL: He didn't decide which variables to
24 use.

25 MR. COHN: You are using apples and oranges --

P1T 003912

1 THE COURT: I will permit him to testify as an
2 expert and reserve on the opinion that he may render as a
3 statistician.

4 MR. EDELL: Can we have Mr. Cohn talk to the
5 witness?

6 THE COURT: Maybe he ought to convey the ruling
7 (Counsel confers with witness.)

8 (End of side bar.)

9 MR. COHN: Excuse me, your Honor, Mr. Edell and I
10 work from different areas.

11 THE COURT: All right.

12
13 DIRECT EXAMINATION CONTINUED

14 BY MR. COHN:

15 Q Dr. Miller, could you tell us what a statistical
16 association is?

17 A That is an association between two factors or variables
18 that is measured by statisticians in a variety of different
19 ways.

20 Q And how does a statistician describe statistical
21 associations?

22 A One way is to use a coefficient of correlations.
23 Another way in certain applications might be a relative risk
24 ratio. There are a number of ways.

25 Each of the measures is like most other statistical

P1T 003913

1 measures, really only measures an aspect in this case of the
2 association.

3 Q In your experience, can statistical associations be
4 applied to any particular individual?

5 A Oh, no. Statisticians deal with samples taken from
6 populations and statistical matters deal with inferences
7 about populations from which the samples are drawn. They
8 can never be extended to deal with any individual member of
9 a population.

10 Q If two facts are statistically associated, does that
11 mean one causes the other?

12 A Not necessarily.

13 MR. EDELL: Your Honor, we are right there.

14 MR. COHN: No. Just general statistical analysis.
15 The question was totally general.

16 THE COURT: I'll permit it.

17 Overruled.

18 A The literature of the statistics is replete with
19 examples of what are called spurious correlations. That is
20 when two variables are correlated, statistically associated
21 with one another and where the examples demonstrate clear
22 lack of causality.

23 Q Give us an example of that.

24 A Some of the ones statisticians are fond of quoting or
25 are the ones about storks and the number of live births of a

P1T 003914

1 town in England, where these two are a series of numbers
2 that are highly correlated, but I don't think most people
3 would conclude, sure, the storks do bring babies.

4 Another example is two series correlated by a
5 statistician some years ago in the sales of chewing gum in
6 the United States and the number of crimes committed highly
7 correlated, but I don't think any reasonable person would
8 conclude the best way to stop crime is to ban the sale of
9 chewing gum.

10 MR. COHN: Can we have a side bar?

11 (The following takes place at side bar.)

12 MR. COHN: I don't want to transgress.

13 The reason I asked for the side bar, we have given
14 Dr. Miller materials that Dr. Mills referred to on atypical
15 carcinoids, and he has reviewed that data and concluded, as
16 a statistician, one cannot derive from that data a
17 statistical association with respect to atypical carcinoid.

18 This has not to do with causation but one step back
19 and again applying basic statistical analysis to the data
20 which was identified by Dr. Mills, Dr. Miller concludes that
21 there is no statistical association between atypical
22 carcinoid and smoking in women based on the data in these
23 articles. He is making no medical judgments or anything
24 else, just taking the data Dr. Mills identified and saying
25 there is no statistical association.

P1T 003915

1 MR. EDELL: How can he do it? No medical training.
2 He has no epidemiologic training. No bio-statistical
3 training and he will review studies and say there is an
4 insufficient amount of information to draw an association.

5 MR. COHN: Statistics.

6 MR. EDELL: A statistician can do anything and draw
7 a causal relationship on any subject regardless of how
8 little or how much he knows, according to what Mr. Cohn
9 says, and that is not what I understand the law to be in
10 terms of expert's qualifications in education or experience
11 in helping the jury.

12 Now, if he will testify on atypical carcinoids I
13 want an additional voir dire because I examined him at his
14 deposition and said, "If this is an insufficient amount of
15 information to show association, how much do you need?"

16 "I don't know how much you need.

17 "How much more would you need?

18 "I don't know.

19 "Approximately how much more do you need?

20 "I don't know."

21 The guy is just not qualified.

22 You may say it goes to the weight of his testimony,
23 it always does, but there has to be a minimal level where he
24 is qualified to testify.

25 I am not going to say he is not qualified to look

P1T 003916

1 at the statistical information, see how the statistical
2 information was run and see whether or not it was run
3 properly, see whether or not the numbers were added
4 incorrectly or not. That is a statistician. He teaches
5 math.

6 MR. COHN: That is not a statistician. If he
7 listened to the testimony he would know.

8 MR. EDELL: I asked him directly the question on
9 the difference between him and the epidemiologist.
10 Epidemiologists are involved in the determination of disease
11 in human beings. That is not what he is involved in, Judge.

12 I don't think you can come in here and bring in
13 somebody who has written a paper for lawyers and done
14 analyses for lawyers and wave a magic wand and, puff, you
15 are an expert in bio-statistics or epidemiology.

16 MR. SIRRIDGE: He is not.

17 The studies he talks about being epidemiology are,
18 in fact, not --

19 THE COURT: Let us not do it. I have a specific
20 objection to a specific witness and I want to know how he is
21 qualified to give this opinion if he is a statistician.

22 MR. NORTHTRIP: Let me add: What Mr. Cohn is
23 talking about now is not causation. He is talking about
24 statistical association. Does this data add up to
25 statistical association.

P1T 003917

1 In fact, on the Surgeon General's Advisory
2 Committee there was a statistician and that was the role,
3 being involved in the epidemiology. And there has been and
4 will be further testimony in that regard.

5 Certainly he is qualified to give an opinion as to
6 whether or not data adds up to statistical association.

7 THE COURT: If what he is going to say is there
8 weren't enough cases to draw a conclusion --

9 MR. COHN: He will say there were enough cases and
10 they were not -- just anecdotal records.

11 THE COURT: How does he know?

12 MR. COHN: He reads them. That is what they say.

13 The point is, as a statistician he knows what an
14 epidemiologic report and study is. He will say these are
15 isolated, not random samples of doctors reporting their
16 experience and you can't come up with a statistical
17 association. What I see here on these articles, which I see
18 what Dr. Mills relied on.

19 THE COURT: I could understand him saying you need
20 X number of cases, 30 cases or 40. But what you are
21 suggesting he does an analysis of the contents in order to
22 make a judgment and he is not qualified to do it.

23 MR. COHN: Analysis of what?

24 THE COURT: Of the content of the medical reports.

25 MR. COHN: All the medical reports say -- and I saw

P1T 003918

1 so many patients and they had this disease and some smoked
2 and some didn't or I didn't know what they did.

3 He is taking at face value the data in these
4 reports.

5 THE COURT: Not analyzing contents?

6 MR. COHN: Not making any decision whether the
7 people had the disease the doctors say or not. He looks at
8 the data, says, okay, I looked at the report. It is
9 anecdotal, there are no case controls. We know very little
10 if anything else about these people but that is not
11 important. He looks and says, from this data there are too
12 few cases and there is no statistical randomness. You
13 cannot say there is statistical randomness.

14 THE COURT: I think he has the right to testify as
15 a statistician, the number of cases he thinks would be
16 statistically significant.

17 MR. COHN: He can't?

18 THE COURT: He is saying this is not enough. But
19 he can't go to the quality of the information or contents --

20 MR. COHN: Quantity or quality? He can say I read
21 this stuff and accept everything said in here. It doesn't
22 add up to a statistical association. That is what he will
23 say. It doesn't require him to analyze it as a medical
24 doctor. He is saying you can't come up with it. He does
25 not -- he is not going to say there is no statistical

P1T 003919

1 association between smoking and lung cancer.

2 THE COURT: Well, I am in the same position as
3 before. I want to hear the foundation for the opinion
4 before he is asked for his opinion and I want to find out
5 whether he is acting within the area. Lay the foundation
6 first.

7 MR. SIRRIDGE: Let me say the foundation has been
8 laid for an established area and background and expertise in
9 sampling and the aspects of statistical associations. The
10 fact that these studies were not random populations is a
11 very important factor to a statistician. He has to explain
12 that these were not randomly selected populations, aside
13 from the pure numbers, so that is clearly within his area
14 and he can testify about it.

15 He will not say Dr. Mills wasn't right saying this
16 wasn't atypical carcinoid versus small cell. He is taking
17 numbers as they exist and --

18 THE COURT: I have not heard him do it.

19 MR. COHN: I wanted to -- not to transgress your
20 Honor's rulings, but on the other hand, I want to make
21 sure --

22 THE COURT: Before you ask him the opinion
23 question, I want to hear what the analysis is that he did
24 and I will decide.

25 MR. EDELL: I do not agree he has the

P1T 003920

1 qualifications to do this because he is not an
2 epidemiologist, not a bio-statistician.

3 THE COURT: I will tell you how I am looking at it.
4 As a statistician he can say if there were only cases that
5 is not statistically significant and, second, reach a
6 conclusion -- I don't know it yet --

7 MR. COHN: Your Honor, when you say -- this man has
8 a Ph.D in statistics, has done statistical methodology with
9 exactly the same kind of methodology as applied to
10 epidemiology. There is no magic.

11 The statistician on the Surgeon General's Advisory
12 Commission had a Master's degree.

13 THE COURT: But he didn't work alone.

14 MR. COHN: I am saying they thought it was
15 necessary to have a statistician.

16 And the first choice -- I will get the document,
17 it's in the evidence. The first choice of the statistician
18 was an insurance company actuary.

19 MS. WALTERS: I think before they get into the
20 discussion of the medical articles they should have to lay
21 the foundation. There was a certain number of cases, that
22 would be enough.

23 MR. COHN: That is irrelevant.

24 THE COURT: I will let them lay the foundation as
25 they think is appropriate.

P1T 003921

1 (End of side bar.)

2
3 BY MR. COHN:

4 Q Dr. Miller, did we provide you with a number of articles
5 dealing with the subject of atypical carcinoid and women?

6 A Yes, you did.

7 Q And have you read Dr. Mills' testimony --

8 A Yes.

9 Q -- in this case?

10 A Portions of it that dealt with the articles.

11 Q Have you read the articles that he referred to in his
12 testimony?

13 A Yes.

14 Q All right.

15 And having read those articles, have you formed an
16 opinion, just answer yes or no, as to whether or not there
17 is a statistical association between cigarette smoking and
18 atypical carcinoid in women?

19 A No. I cannot form an opinion either way from those
20 articles.

21 Q Now, what was the basis of your analysis of these
22 articles which led you to that conclusion?

23 A The basis --

24 MR. EDELL: Your Honor, I thought there would be a
25 foundation laid but --

P1T 003922

1 THE COURT: I think that is what we are doing now,
2 I hope.

3 A The basis was to determine whether or not there was a
4 sufficient statistical validity or basis for, in those
5 articles, for estimating of any parameter. And I found
6 that --

7 THE COURT: Before you tell us what you found --

8 A The basis was whether or not --

9 Q What kind of statistical analysis did you perform on
10 those?

11 A I didn't perform any analysis. I asked myself the
12 question of whether the data in those articles was
13 satisfactory to a statistician as a way of determining
14 whether or not any estimate of any parameters of some
15 population can be made.

16 Q Did you, in coming to that conclusion, consider the
17 nature of the data which was reported in that -- in those
18 articles?

19 A Any statistician would have to consider where the data
20 came from, whether or not -- how they were selected, and
21 whether or not there was a stated population from which the
22 data were selected.

23 Q And would the number of cases be significant?

24 A The number of cases plays a role but it is not the only
25 consideration.

P1T 003923

1 Q And what -- did you find that there were standards,
2 statistical basis lacking in these studies?

3 A Yes, I did.

4 Q What was lacking?

5 A Well, there was no definition of a population in any of
6 the studies. There was no statement as to whether or not
7 the individuals reported on were samples selected from any
8 population and, if so, how was the sampling done.

9 In other words, there was a clear lack of evidence
10 of any representative or representatives -- that the
11 individuals represented any group in particular and
12 statisticians always look for that.

13 Q And did you see any case controls in these studies?

14 A That is a specific way of saying what I just said. By
15 the fact there were no case controls, there were no
16 standards by which statisticians would support an estimate
17 of any kind.

18 MR. COHN: Your Honor --

19 THE COURT: I will permit it.

20 Objection overruled.

21 MR. COHN: Thank you.

22 Q Dr. Miller, in your opinion is there a statistical
23 association between cigarette smoking and -- in women and
24 atypical carcinoid?

25 A I cannot give an opinion as to whether there is or not.

P1T 003924

1 I have not seen any data that would allow me to
2 arrive at any conclusion one way or the other on it on this
3 statement.

4 Q Now, Dr. Miller, turning your attention now to the data
5 you received from the American Cancer Society or data that
6 was received from the American Cancer Society, I believe you
7 testified that you were provided with this data by counsel
8 who obtained it through discovery?

9 A Correct.

10 Q And when was the first time that you tried to obtain
11 that data?

12 MR. EDSELL: I don't see how that is relevant to
13 anything.

14 THE COURT: Sustained.

15 Q Dr. Miller, do you know how that study, that survey was
16 conducted?

17 A Yes. From reading accounts that were published in
18 literature and from information that was sent to me or
19 provided to me when I received the tapes containing the
20 data.

21 Q And could you give a general description of how this
22 survey was conducted?

23 A Yes. I believe I can.

24 In 1959, the American Cancer Society enlisted the
25 aid of a number of volunteers in 25 states. I believe there

P1T 003925

1 were something in excess of 20,000 of them.

2 These volunteers were then asked to recruit
3 respondents, that is, people who were willing to give
4 information about themselves. They went about the process
5 of recruiting. One can assume from what one reads that
6 there were friends and neighbors and relatives and other
7 people known to the volunteers and all in all they recruited
8 over a million men and women in the states to participate in
9 this study.

10 These respondents, that is, these participants --
11 and incidentally I believe that included all or most of the
12 volunteers themselves, they were all respondents. These
13 respondents then were asked to fill out a rather lengthy
14 written questionnaire about themselves and their medical and
15 other background in history.

16 Subsequent to that these people were followed up
17 through most of the period although there was a hiatus for a
18 while in the follow-ups, up until about 1973. And in the
19 follow-ups were recorded any changes of name or address or
20 any changes in cigarette smoking that they did, and also if
21 a respondent died, information was gotten as to the cause of
22 death as recorded on the death certificate, and it is my
23 understanding that they followed up on many of the death
24 certificates, but going back to the hospital or the
25 attending physician to verify the cause of death and that

P1T 003926

1 sort of thing.

2 Q Now, Dr. Miller, would it help the jury understand what
3 you did if they could see the questionnaire that was given
4 to these respondents?

5 A Yes. I think it would be very useful to review it
6 because it is unique in these kinds of studies.

7 MR. COHN: Your Honor, we have here Defendant's
8 Exhibit, Joint Trial Exhibit 3031 which is blown-up version
9 of the questionnaire.

10 THE COURT: Any objection, Mr. Edell?

11 MR. EDELL: This is simply a portion or --

12 MR. COHN: The whole questionnaire is here. It
13 should be in order.

14 THE WITNESS: It is out of order.

15 THE COURT: No objection?

16 Offering it in evidence?

17 MR. COHN: Yes, in evidence.

18 THE COURT: In evidence.

19 MR. COHN: As soon as we get it organized.

20

21 BY MR. COHN:

22 Q Dr. Miller, I would like you to come here and kind of
23 hold this up. It is too big for the easel.

24 MR. EDELL: There are a couple of stands back here.

25 MR. COHN: We have a stand here but --

1 MR. SIRRIDGE: You need two of them.

2 A I would like to describe for the jury the kinds of
3 questions that were covered on these questionnaires. It
4 started out with general information.

5 Incidentally, I should start out by saying there
6 were two questionnaires, one for women and one for men.
7 They were alike in most respects but they differed in some
8 respects.

9 The one for women contained information about
10 diseases and conditions peculiar to women. Ones for men
11 contained information about occupational exposures whereas
12 the one for women did not. Outside of those differences
13 they were basically the same.

14 This is the one for women. Started out by asking,
15 name, date of birth, height, marital status, whether there
16 was a previous marriage, kind of introductory things you
17 would normally ask. We did not have these questionnaires.
18 We had a computer tape which had recorded on it, the data
19 that were put in by the respondent. So while there is a
20 line here for name, we did not have that information, so the
21 confidentiality of the respondents was maintained.

22 We could separate them because up here there was a
23 person number, a unique number given to each respondents and
24 that allowed us to identify this is the respondent that had
25 all these answers.

P1T 003928

1 There was also division, unit and group number,
2 which are codes relating to where they lived and what
3 locality, what state, I think it went down to county level.
4 Unfortunately, we didn't have the codes. We attempted to
5 get them but the American Cancer Society study was done many
6 years ago, couldn't come up where the coding. So we had the
7 numbers but we didn't know what they meant.

8 Going on, as you can see, the questionnaire
9 consists of groups of questions that are -- that have things
10 in common. So the first deals with family history in
11 relation to cancer and asks about parents and grandparents,
12 whether they had cancer, if so, what type, whether they were
13 alive or dead. If they died, what age, and separated the
14 grandfathers in the mother's and father's side and asked the
15 same questions.

16 Went on to ask similar questions about brothers and
17 sisters. Asked the question about twinship. Did you have a
18 twin sister, when you were born, how old with your parents.

19 Then it went into a section dealing with history of
20 diseases starting with cancer. Did you have cancer? If so,
21 what type, what was the date of the first treatment, and it
22 went into pneumonia, tuberculosis, bronchitis. Poliomyelitis
23 and I won't burden you by reading every one. You can see
24 them.

25 The questionnaire goes on, and goes next to the

P1T 003929

1 question of surgical operations, whether you had one, if so,
2 what kind.

3 Goes into x-ray and neuroscopy and goes into
4 present physical complaints. Do you have any complaints
5 now, and list a whole large number of common complaints and
6 in each case asks whether or not the respondent had that
7 complaint and if so, a question dealing with the severity or
8 frequency of the complaint, depending upon the specific
9 detail.

10 Sorry.

11 Q Okay.

12 A Then questions about, have you seen a doctor,
13 difficulties with constipation, sick at the present time,
14 went into a great deal of detail about the health of the
15 respondents.

16 The questionnaire goes on from there.

17 This is the section specific to women questions
18 relating to breast and female genital organs, usual
19 questions asked of women by doctors. You can see what they
20 are.

21 Then it goes into things people do in general.
22 Starts out with exercise. How much sleep do you get and
23 there are a number of questions dealing with smoking. Do
24 you now smoke? If so, how many cigarettes do you usually
25 smoke a day?

P1T 003930

1 A lot of detail. About how much do you inhale
2 when smoking cigarettes, what type do you smoke, filtered
3 without filters, what brands. How old were you when you
4 started smoking cigarettes. If you do not smoke cigarettes,
5 did you ever smoke cigarettes regularly. If yes, how long
6 has it been since you last smoked, how many cigarettes did
7 you smoke, why did you stop smoking.

8 Then it goes on into questions about the ingestion
9 of foods and mentioned a wide variety of common foods we eat
10 and asks the respondents to say how many days a week do you
11 eat each of the following foods and you can see what some of
12 them are.

13 I think we are all glad this is the last page of
14 the questionnaire. But I think it is important that we
15 understand the nature type and variety of subjects that were
16 covered.

17 Then it goes into specific questions about food
18 relative to fat, fried foods, in grease, lard, oil, salt,
19 pepper, mustard, spices. These are all things that deal
20 with the specifics of food intake and it asks similar
21 questions about things you drink.

22 How many cups, glasses or drinks of various
23 beverages, milk, coffee, tea, soft drinks and some alcoholic
24 beverages. When drinking coffee tea or soup, do you take it
25 hot or not so hot.

P1T 003931

1 Do you have -- do you avoid certain foods or drinks
2 because they give you indigestion. Then it goes to
3 over-the-counter medicine, aspirin, vitamin pills, sleeping
4 pills, so forth asked about their use.

5 Finally a medical check-up, does he have one every
6 year.

7 It ends with miscellaneous questions dealing with
8 occupation or if retired, previous occupation. Questions
9 about your feeling of the respondent as to whether or not
10 was respondent under pressure or nervous tension.

11 Molds and warts. Sores that won't heal. Lost
12 teeth. Dental place. Do you live in a house with a person
13 who had cancer.

14 Has a child of yours had cancer.

15 Goes into religion, where you were born, extent of
16 your education, and finally it asks whether the person,
17 whether you filled out the questionnaire yourself or whether
18 somebody filled it out for you. Because I guess in some
19 cases there must have been people who were ill or indigent
20 or illiterate and could not fill it out and they were asked
21 the questions orally and somebody else wrote the answers
22 down.

23 That is the extent of what the American Cancer
24 Society covered in their initial questionnaire.

25 Q Thank you, Doctor.

P1T 003932

1 You may take your seat again.

2 A (Witness complies.)

3 Q Dr. Miller, in connection with the material you reviewed
4 with respect to the American Cancer Society study, was there
5 any indication of why the questionnaire had so many
6 questions?

7 A There was no specific indication but it is obvious from
8 looking at these questions that they all relate to possible
9 theories, hypothesis or factors that might be involved in
10 cancer.

11 The American Cancer Society did state in the
12 literature that they did this purpose in an effort to gather
13 data about the various factors that might be involved in
14 cancer.

15 Q Now, given your experience in conducting surveys, Dr.
16 Miller, is there anything that is significant about this
17 questionnaire, that you believe the jury should know about?

18 A Well --

19 MR. EDELL: Your Honor, in terms of his
20 qualifications of opinion surveys or epidemiological
21 surveys?

22 THE COURT: As a statistician.

23 MR. CONN: Not opinion surveys but surveys as a
24 statistician.

25 THE COURT: Permit it.

P1T 003933

1 A Yes. Part of my duty with Opinion Research Corporation
2 and I reviewed, I don't know how many questionnaires and
3 they all have certain things in common. Doesn't matter what
4 the field of application is.

5 One of the issues that one is concerned about with
6 any survey questionnaire is, are you asking questions that
7 involve recall.

8 This questionnaire has a number of questions that
9 ask the respondents to remember, and we know from our
10 experience with survey research, that when you ask people to
11 remember the details of their everyday life, it is a little
12 hard.

13 I would ask people in this courtroom or members of
14 the jury for -- if they can remember exactly what they ate
15 yesterday for example and how large the portions were. I
16 think we all have a little difficulty with that, work we did
17 at ORC showed even businessmen that we had interviewed
18 couldn't remember the brands or make of car that they rented
19 the last time they rented a car on a business trip and that
20 might have been as recently as a week or two ago. Recall
21 questions are a particular problem.

22 The survey did ask a number of questions about
23 food, over-the-counter medicines, what you drank, how much
24 and so forth. These are the kinds of recall questions I am
25 talking about.

P1T 003934

1 So we do have some problems which are faced in a
2 lot of surveys which were certainly faced here with recall
3 questions, the answers to which are not as precise as we
4 wish they could have been.

5 In a second area we have a few questions that
6 dealt -- that were very subjective, very difficult to
7 compare the answers of two respondents to see if one person
8 was more or less.

9 Let me give you a couple of examples. There was
10 one dealing with stress or tension that you might recall.
11 The question was asked -- I can only paraphrase it.

12 Q Maybe we can hold it up again.

13 A That would be helpful, thank you.

14 Q Okay.

15 A Let me see if I can read it.

16 MR. CONN: No. Wrong one.

17 It is up here?

18 THE WITNESS: Yes. Number two under miscellaneous.
19 The question specifically was asked, many people complain
20 that their work or home situation puts them under nervous
21 tension. How much pressure or nervous tension do you feel
22 you were under. Answer categories were, none, slight,
23 moderate, severe.

24 One person who feels a little nervous might have
25 said severe. Another person with what might clinically have

P1T 003935

1 been determined to be the same amount of pressure or tension
2 might have thought that that was slight. In other words,
3 the answer is subjective.

4 If you say severe and you say slight that doesn't
5 mean that you are really under different amounts of
6 pressure, just your own subjective judgment as to how much
7 you are under. You are -- these questions require
8 subjective answers, do create some difficulty and some
9 variability but they do contain some information also.

10 There was another one similar to that and that was
11 the amount of exercise. I don't know if we have it handy or
12 whether we should do it acapella -- want me to spell it, I
13 can't.

14 Q Under habits?

15 A Yes. How much exercise do you get at work or play,
16 none, slight, moderate, heavy. I know a lot of guys, and I
17 may be included in that group, who when they get up off the
18 couch that is heavy exercise. I am being a little
19 facetious.

20 The point is that your moderate exercise might be
21 my slight exercise. Somebody's heavy exercise might be
22 somebody else's moderate. All depends on how you look at it
23 and what you are used to. Just because one said moderate
24 and another said slight doesn't mean this person gets more
25 exercise than that person. That is the point I make about

P1T 003936

1 subjective questions.

2 There is a third point I would like to bring out.
3 As extensive and encompassing as these questionnaires were,
4 there were a number of issues that might be related to the
5 subject of cancer as a disease, that were not asked.

6 I know that for a fact because it is my
7 understanding that the American Cancer Society is now in the
8 process of doing a follow-up study and some new questions
9 have been asked. Questions relating to the use of certain
10 vitamins, vitamin A specifically.

11 Questions that deal with the women's questionnaire
12 did not include anything on occupational exposure. There
13 might have been toxic hazards of one or another at the
14 workplace and that is included in the follow-up.

15 Since this study was done a lot of attention has
16 been paid in the newspaper and in the scientific literature
17 to the question of radon gas, radioactive gas, there are
18 certain rock formations in certain parts of the country.
19 There was nothing that allowed us to locate these people
20 geographically because we couldn't find the code, so we were
21 unable to determine what that effect might be.

22 Also, no matter what kinds of studies a
23 statistician or any other scientist might perform, there are
24 always variables. Always factors that in today's state of
25 knowledge, in today's state of science might some day later

P1T 003937

1 prove to be important but we don't know anything about them
2 today.

3 Radon was a wonderful example of that. Because in
4 1959 I don't think anybody knew much about it or suspected,
5 whereas today it has become an important possible factor in
6 the area of several diseases.

7 So there is the whole list of factors that we don't
8 know about today that might be important next week, next
9 month or next year. I don't criticize the study for not
10 including them. Nobody could have included them but we must
11 recognize they are not there.

12 Q Dr. Miller, I think you testified you did not receive
13 the questionnaires?

14 A I did say I did not receive the actual questionnaires,
15 that is right, sir.

16 MR. COHN: Excuse me a moment.

17 Q You received, Dr. Miller, the information or the data in
18 the form of tapes, correct?

19 A Yes. Computer tape, very similar to what you are
20 holding.

21 Q Let me show this to you, is that the kind of tape that
22 you received which included the data?

23 A Yes. It even has a label that says ACSFN2 so it is
24 probably a copy of one of them.

25 You may have seen tapes like this. A magnetic tape

P1T 003938

1 and contains on it in the form of little magnetic dots, you
2 can't see images that a computer reads and are translatable
3 into numbers and letters.

4 Q How was the data from the questionnaire put on these
5 tapes?

6 A Well, given the technology of that time, I assume what
7 they did was take the questionnaire, this is what we all did
8 in survey research in general. Take the questionnaire to a
9 key punch operator who would key punch, keyboard like a
10 typewriter. Key punch the information in the questionnaire,
11 being careful to put it in certain places already defined in
12 advance called filters, and that makes little holes in
13 cards.

14 Then you pass this deck of cards through a computer
15 and the computer generates this tape.

16 Q Now, about when did you receive these tapes, Dr. Miller?

17 A Let me see, I received these tapes early in 1986. I
18 think it was February or March.

19 Q And then what was the first thing you did when you
20 received the tapes?

21 A First thing I did at that time I was at ORC we had an
22 extensive computer department for the purpose of processing
23 questionnaires. And so I went to the head of the data
24 processing department, and I asked him if he could mount
25 these tapes on our computer, and make sure that they were

P1T 003939

1 readable by our computer.

2 Sometimes a tape prepared by one computer is not
3 easily read or perhaps never read properly by another
4 computer. So he performed that exercise and reported back
5 to me that he was able to read the tapes.

6 I then asked him if he could get me certain
7 information off the tapes so I could satisfy myself that he
8 was able to read them accurately and completely. We looked
9 at where the questions appeared on the tape, where the
10 answers to the questions appeared, tabulated all of them to
11 make sure that the answer categories given on the tape were
12 the right ones so if one answer category required none,
13 slight, moderate, strong, that we had answers in those
14 categories and not others.

15 If the question asked for the woman's weight I
16 didn't want to see any 3,000 pounds limit or any ten pounds
17 limit, to make sure the numbers were reasonable. We did a
18 great deal of work in characterizing the numbers on the tape
19 to make sure that they jived and were reasonable to what we
20 would have expected given the questionnaire.

21 Q So I take it it, the first thing you did was to verify
22 that the data from the questionnaires were, these people
23 were on the tapes?

24 A First, we verified that the data were on the tapes and
25 then we verified that they made sense with respect to what

P1T 003940

1 we expected from the questionnaire and we went a step
2 further and verified that they made sense with respect to
3 how many people we were expected to have.

4 Q How many people were on these tapes?

5 A There were -- of course, we got all of the tapes which
6 included both men and women and that was in excess of a
7 million.

8 When we looked at just the questionnaires filled
9 out by women it was just under 600,000 and we did make a
10 tabulation of that data in a slightly finer breakdown to
11 verify that the numbers we were getting were what we could
12 have expected.

13 MR. COHN: Your Honor, this might be a good time
14 for the morning break.

15 THE COURT: We will take a recess and resume five
16 of 12.

17 THE CLERK: All rise.

18 (Recess taken.)

19 THE CLERK: All rise.

20 (Jury present.)

21 THE COURT: Mr. Cohn.

22 MR. COHN: Thank you, your Honor.

23
24 I R W I N M I L L E R, previously sworn, resumes.
25

P1T 003941

1 DIRECT EXAMINATION CONTINUES

2 BY MR. CONN:

3 Q Dr. Miller, who was in charge of this American Cancer
4 Society survey?

5 A Based upon the papers that I have read it was Dr. E.
6 Keller Hammond. He is now deceased and was the chief
7 statistician of the American Cancer Society.

8 Q Was he a medical doctor?

9 A No. I believe he had a Ph.D in -- I don't know whether
10 it was biostatistics or epidemiology or what it was.

11 Q And is this the American Cancer Society that is often
12 referred to in reports of the Surgeon General's reports?

13 A Yes. This is the American Cancer Society. And this
14 study is referred to in a number of Surgeon General's
15 reports.

16 Q Now, after you verified that the data on the tapes was
17 actually there, did you make a summary of the data
18 concerning women in the study?

19 A Yes, I did.

20 Q And we have a chart of that summary and I would like to
21 show it to you and to the jury.

22 MR. CONN: Your Honor, this is Defendant's Exhibit,
23 Joint Trial Exhibit 3036.

24 THE COURT: Show it to Mr. Edell first.

25 (Counsel views document.)

P1T 003942

1 MR. COHN: Mr. Edell was given a smaller copy of
2 this before, your Honor.

3 THE COURT: No objection.

4 MR. EDELL: I don't have an objection if he uses it
5 as demonstrative evidence.

6
7 BY MR. COHN:

8 Q Dr. Miller, maybe you can come down and explain to the
9 jury what this summary shows.

10 A Okay.

11 This summary shows that the tapes contained data on
12 594,548 women.

13 It breaks the data down into several categories.
14 One category by lung cancer, and the other by smoking.

15 And it shows, for example, that of these 594 plus
16 women, 103,940 of them were smokers, 42,438 of them were
17 ex-smokers, 393,070 of them had never smoked. And that adds
18 up to the total here.

19 Also it shows that of these 594,548 women, 1792
20 were diagnosed during the study as having lung cancer.

21 Q How many follow-ups were included in the data that you
22 looked at?

23 A This included follow-ups, the last data I recall was
24 159,073.

25 Q So the period is '59, when the original questionnaire

P1T 003943

1 was distributed, to 1973?

2 A Yes.

3 Some of the original questionnaires were not
4 administered until early 1960.

5 Q Okay.

6 A So over that period of the study, from '59 to '73, there
7 were 1792 women were recorded as having had lung cancer, of
8 whom 1417 were recorded as having died from the disease.
9 And, of course, the remaining 300 almost 93,000 did not or
10 were not reported in the study as having had lung cancer.

11 Q All right.

12 Dr. Miller, I notice that the number of lung cancer
13 cases among smokers and nonsmokers is almost equal. Is that
14 correct?

15 A There were 816 smokers who were diagnosed with lung
16 cancer during the study and 849 nonsmokers. And when one
17 considers mortality, 667 smokers were reported to have died
18 of lung cancer during the study and 638 nonsmokers.

19 Q Now, Dr. Miller, I believe you testified earlier that
20 one way to express a statistical association is by a
21 relative risk ratio?

22 A Yes, I stated that.

23 Q And did you compute a relative risk ratio with respect
24 to the data that you have on this chart?

25 A Yes, I did.

P1T 003944

1 Q Could you tell the jury how you did it?

2 A Yes. A relative risk ratio is what the name implies, it
3 is a ratio of risks. So first one has to compute a risk or
4 ratio that expresses the proportion of, in this case women
5 who got lung cancer. I did it for the morbidity, people who
6 had the disease, not specifically for mortality, which is
7 the word used for people who died of the disease.

8 I took 816 smokers who were reported as having had
9 lung cancer and divided by 159,040 total smokers and came up
10 with a number expressing what proportion of smokers got lung
11 cancer.

12 Then I did the same thing for the nonsmokers. I
13 took 849 and divided by 393,070, coming up with a proportion
14 of nonsmokers who got lung cancer.

15 It is the ratio of these two that is the relative
16 risk.

17 Q What was the relative risk?

18 A When I did it from these numbers I think it was about
19 2.4.

20 Q That was not adjusted?

21 A Not adjusted for age but the raw numbers you see here.

22 Q In the literature is this relative risk ratio commonly
23 adjusted?

24 A Common to do it, yes.

25 Q Did you compute a risk ratio in this study for almost

P1T 003945

1 600,000 women?

2 A Yes.

3 Q What was the age adjusted relative risk ratio?

4 A 3.85.

5 Q Doctor, about the same number of women smokers and
6 nonsmokers got lung cancer. How come there is a relative
7 risk ratio of 3.85?

8 A We can see it because while the same number of smokers
9 or almost the same number of smokers and nonsmokers got lung
10 cancer, there were fewer smokers in the study, about a third
11 or fewer than that compared with nonsmokers. The relative
12 risk ratio reflects the fact that this number a fewer got
13 lung cancer than this number out of a greater group of
14 women.

15 Q When you took into consideration smoking, lung cancer
16 and age, the relative risk changed from when you just took
17 into consideration smoking and lung cancer?

18 A Yes. Taking into account the factor age changed from
19 about 3.4 to 3.85, about.

20 Q Does the age adjusted relative risk ratio, you have
21 computed, take into effect any other factors other than age,
22 obviously sex here because it is women, lung cancer and
23 smoking?

24 A No, sir. Those are the only factors that could possibly
25 be included in the calculation that I performed.

P1T 003946

1 Q Now, is there a well-established statistical method
2 which can be used to reflect associations with many factors?

3 A Yes, there is.

4 Q What is that?

5 A It is called in general multi-varied statistical
6 analysis. Specifically one of the major methods in the body
7 is called multiple regression.

8 Q This study, did it not contain data of many other
9 factors besides age, smoking, lung cancer, and death?

10 A Yes.

11 Q And women?

12 A Yes. And the fact some were men and some were women,
13 yes. When we went over the questionnaire we saw that the
14 study was capable of producing information about many, many
15 other factors in addition to the ones you named.

16 Q And did you construct a table of sort of categories of
17 variables that we might show the jury?

18 A Yes, I did it in preparation for doing this analysis.

19 MR. COHN: Mr. Edell.

20 (Counsel views chart.)

21 MR. EDELL: I have never seen it before but...

22 MR. COHN: This is 3035 joint trial exhibit.

23 THE WITNESS: I am trying to get out of your way.

24 Q Dr. Miller, could you explain how this chart was -- what
25 this chart indicates?

P1T 003947

1 A Yes, sir. This is the list, not of all the variables or
2 factors that we defined preparatory to doing our analysis,
3 but it shows the categories they belong to. There were 350
4 variables and it would be too much to give a complete
5 listing, but I wanted to give the jury a feel for what they
6 encompass. All of these variable included data that came
7 from the American Cancer Society questionnaire or from the
8 follow-ups that were done.

9 We had one ground of variable that dealt with
10 personal characteristics. If you recall from looking at the
11 questionnaire a little while ago, there were age and weight
12 and many other personal factors. We defined 13 variables
13 that dealt with it. Cancer history there were four
14 variables that dealt with it. Four important but
15 nevertheless technical when he eliminated 18 of the
16 variables relating to cancer history because we were trying
17 to statistically relate factors describing these women to
18 lung cancer. And if you put cancer as one of the factors,
19 it might well have been lung cancer, so you are trying to
20 relate lung cancer to lung cancer. So in the interests of
21 conservatism we left out variables that clearly could have
22 been lung cancer.

23 Going down the list further, the general medical
24 history, if you recall looking at that, there were ten
25 variables defined to describe the responses on the

1 questionnaire to that, 62 variables to describe female
2 medical history, 24 for surgical procedures, 24 for current
3 complaints, if you recall that list of current complaints,
4 headaches, dizziness, longevity of family members, eight
5 variables dealing with the parents, grandparents, sons and
6 daughters, follow-up data, how often did they move,
7 follow-up dealt with moving, and 17 variables to describe
8 those, 41 described background of the women involved, her
9 education, type of residence, so forth, food intake, 46
10 variables, beverage intake, 18, drugs used, six, personal
11 habits, exercise sleep, et cetera, nine. The variables
12 describing smoke, whether or not she smoked, how many filter
13 tips, inhalation, that sort of thing, 41 variables for a
14 total of 350.

15 I must hasten to add you have seen the
16 questionnaire and you wonder how did anybody get 350
17 variables out of the questionnaire. Some of the questions,
18 if you recall, had several answer categories; frequent --
19 seldom, frequent, all the time, things like that. When you
20 have qualitative questions like that with several answer
21 categories, statisticians have to define more than one
22 variable to describe all the answer categories. So there
23 are really more statistical variables than there were
24 questions on the questionnaire for that reason. But,
25 nevertheless, they cover a wide variety of pieces of

P1T 003949

1 information about the women and the study.

2 Q Thank you, Doctor.

3 Now, I think you testified that after you verified
4 the data you did the relative risk ratios and then you
5 performed multiple regression analysis?

6 A Yes.

7 Q If you can take your seat again, please.

8 A Yes.

9 (Witness complies.)

10 Q Doctor, could you tell us what multiple regression
11 analysis is?

12 A Yes.

13 First, I would like to talk about simple regression
14 analysis, so we can get the idea.

15 Q Doctor, if you have visual aids use them.

16 A I do have visual aids to describe it and, if I may, I
17 would like to use them.

18 Q Go ahead.

19 MR. DECKER: Marc.

20 MR. EDLL: I understand it clearly.

21 Q Okay.

22 A I realize we are using technical terms; regression
23 analysis. But let us try to see if we can understand the
24 idea behind it because I think it is important that we do it
25 in order to try to understand what the results mean.

P1T 003950

1 These two charts did what can be called simple
2 regression analysis. By simple regression analysis we
3 simply mean we are trying to relate two variables, one to
4 the other.

5 If you look at the chart on the left, you will see
6 two factors, one I labeled X, and the other I labeled Y, to
7 give you an example that might help follow what I will say.

8 If you recall, earlier this morning I talked about
9 storks and number of live births, chewing gum and crime as
10 examples of variables that are related, whether or not there
11 is any sense to that relation, they are still statistically
12 related.

13 Let me try another one that I think lends itself
14 nicely to describing this situation.

15 Let us suppose, for the sake of this example, some
16 man came down from Mars or some other place, doesn't know
17 very much about what goes on on earth, but he is a very
18 intelligent fellow and he observed and is interested in the
19 game of basketball.

20 He observed by just looking at data, he doesn't
21 know the rules, but looked at all the data and observed the
22 more a basketball player weighs, the more points he scores.
23 So he puts together a team of the heaviest men he can find
24 and, of course, he doesn't do very well. Until he finds out
25 that it is the tall men that do better at basketball.

P1T 003951

1 Generally when a man is taller he weighs more because there
2 is more of him.

3 So what we have here is three variables, two of
4 which are driving the relationship of another two or one of
5 which is driving the relationship of another two.

6 I would like to use that example to illustrate what
7 is going on in this diagram, if I may.

8 Let us imagine, for example, that this X visual is
9 the height of the basketball player and assume that the Y
10 visual is the average number of points he scores per game.
11 The little pink dots simply represent different basketball
12 players. And we have to ask ourselves why is this dot here
13 and why is that dot there? What does it mean?

14 Let us take a typical dot. Take this one because
15 it is easier to see it. It is more or less off by itself.
16 This dot is as far to the right because that is how tall
17 that basketball player is. You can think of a line here and
18 this distance between my fingers is the height of the
19 basketball player. This dot is as high as it is because
20 this particular basketball player scored that many points on
21 average per game. He, obviously, is a pretty tall fellow
22 and scores a lot of points. This is the biggest point
23 scorer and also the tallest man.

24 Doesn't have to be that way because here is a
25 fellow of a certain height scoring this many points, the

P1T 003952

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1 distance between my two fingers, and another fellow about
2 the same height and he scores more points.

3 The question that we want to ask is not what does
4 an individual do. The question we want to ask is, is there
5 a statistical relationship, is there an association, between
6 the height of a basketball player and the number of points
7 he scores?

8 And if we look at all these dots on this chart, we
9 see that they do seem to follow a pattern, generally but not
10 always, when a man is taller he scores more points, we can
11 describe that pattern by putting a straight line through
12 these points, that is this red line you see here, and we can
13 use that line as a way of representing the relationship.

14 Now, the question arises -- given any set of
15 points, you can always stick a line through it. The
16 question is, how good is that line? How well does it
17 represent the points that you see?

18 Another way of asking the question is to ask, how
19 good is the relationship? Is it strong or is it weak?

20 Statisticians have developed a number that
21 describes how good a regression relationship or a
22 statistical relationship is. That number we call the index
23 of association. There are other names for it in the
24 literature but I won't burden you with any more jargon than
25 I have to. Let us call it the index of association. And it

P1T 003953

1 is a number that takes on -- its smallest value zero and the
2 biggest it can be is one.

3 This index of association is close to one when the
4 point, when the data, or close to, in this case, a straight
5 line. So here is an example of a regression relation -- a
6 statistical association, if you will, where the index of
7 association is close to one, because these points have a
8 nice linear trend that is reasonably well described by this
9 straight line.

10 Now, if we look at the chart on the right here, we
11 also have another association. You can still think of the Y
12 direction as the average number of points that the player
13 scores in the game, but suppose that X is the mother's age.
14 You wouldn't really expect that to be terribly important
15 with how many points. This is all imaginary.

16 It is for the purpose of getting the idea. If we
17 presented the data, we would get a spread of points and
18 probably the line drawn here is probably as good a line as
19 any that we can draw. But you can see it doesn't describe
20 the relationship very well.

21 If I say well, a fellow whose mother is this age
22 scores that many points, I have a lot of examples of
23 basketball players with -- whose mothers are about that age
24 but who score different number of points, so this is a very
25 weak statistical relationship.

P1T 003954

1 In this case, the index of association, if
2 computed, and there is statistical formulas in the
3 literature for computing it, that index of association would
4 come out to be a number very close to zero.

5 Now, these data points were adapted from some
6 statistical work I did on a totally different matter that
7 they are not exactly the same, but the work I did had an
8 index of association in this case of about .4 which is
9 pretty close to 1, and in here when you actually calculated
10 it, it was .02.

11 So here is an example of a regression, simple
12 regression, because it only involves two factors where the
13 index of association is a number near 1 and here is an
14 example of a simple regression where the index of
15 association is a number close to zero.

16 Q Now, Dr. Miller, taking the basketball analogy a little
17 further, what happens when you also want to understand what
18 effect say speed, experience, number of years playing,
19 coordination, how long somebody has been coached. Taking in
20 say several other factors what do you do then?

21 A If you indulge me, I would like to deal with one more
22 first and then we will talk about what happens when you put
23 in the rest.

24 Suppose we had one more factor. You suggested
25 speed and that is as good as any.

P1T 003955

1 Suppose we were interested and look at this chart
2 first, if you will, suppose we are interested not only in
3 the basketball player's height, but how fast he is. We can
4 do it by having him run a quarter of a mile and see how much
5 time it takes.

6 We would need another direction in which to
7 describe it, so -- where is the pointer?

8 Q Right there.

9 A Thank you.

10 We need another direction to describe it, so we can
11 think of a line or axis coming out into the room from this
12 point and say well, if his speed is good speed he would be
13 here and if it were slow speed he would be closer to the
14 board.

15 Now, these points instead of lying on the flat
16 surface would be out here in the room. So we would have
17 these points out here, and each point would tell us his
18 height, his speed, and his number of points scored per game,
19 the point here we could identify if we knew where it was.

20 We have a mess of points in the room and the
21 question is can we associate them. Can we find a
22 surface -- if I may borrow a piece of paper here. Can we
23 find maybe a plane that they all lie on or close to in this
24 space of the room.

25 We can use the exact idea, same idea of index of

P1T 003956

1 association just as we had before, to measure how well that
2 happens.

3 If there is a good strong association, even though
4 we have now another factor, we will still get an R square
5 close to 1. And if the points are spread all over space we
6 can get a R close to zero.

7 Q Saying R square?

8 A Index of association. Forgive me for doing that.

9 R square is a symbol we use to stand for index of
10 association. We are all lazy and don't want to say that all
11 the time.

12 You also asked I believe, Mr. Cohn, what if there
13 were other factors? What if there were a factor where would
14 I draw the axis. I would need a dimension and it would be
15 difficult for me to imagine. If there were 20 factors I
16 would need 20 dimensions and it would be impossible for us
17 to imagine. But that is what mathematicians deal with all
18 the time. Spaces of many dimensions. You don't have to see
19 them or imagine them to still be able to compute the number.

20 There are formulas that allow you to compute an
21 index of associations no matter how many dimensions there
22 are. And the index of association still carries the same
23 old idea, if it is a number close to zero there isn't much
24 association. Whereas, if it's a number close to 1 there is
25 a lot of association.

P1T 003957

1 Q Thank you, Doctor.

2 Now, you said you performed multiple regression
3 analysis on the data you obtained from the American Cancer
4 Society. Correct?

5 A Correct.

6 Q And what was the first thing you did when you started
7 your multiple regression?

8 A The first thing I did was to take a sample of the almost
9 600,000 women on whom data had been collected. This is very
10 akin to what is done in an epidemiological study. I
11 included all of the women who were diagnosed as having lung
12 cancer, some 1700 plus of them if you recall from the
13 previous chart.

14 And for each one of these women using the computer
15 to do it, we randomly selected other women who were not
16 diagnosed as having lung cancer so the sample contained two
17 non-lung cancer for every lung cancer one approximately,
18 because the process of selecting random numbers on a
19 computer is close but not exact.

20 And the non-lung cancer women were chosen as it
21 were with blindfolds on because it was done through the use
22 of a random number scheme in a computer.

23 Q Do you have a chart showing the results of regression
24 analysis on that sample?

25 A Yes. Perhaps before showing the chart it might be

P1T 003958

1 useful to say the one next thing I did which was to divide
2 the women into age groups by five year age groups. So as I
3 recall, in order to be eligible to participate in this study
4 a person had to be at least 30 years of age. We started
5 with 30 and took women whose ages were 30 to 34 to the
6 nearest year and 35 to 39, 40 to 45, et cetera. So we
7 divided the women into five-year age groups in each sample.

8 Then I did regressions separately on these women by
9 age group from the sample.

10 Q All right. I think we have a sample here that is of the
11 age group 55 to 59?

12 A Yes. We do have a chart on that?

13 Q Okay.

14 MR. COHN: Your Honor, this is 3038, Defense Joint
15 Trial Exhibit.

16 MR. EDELL: This is the regression analysis.

17 MR. COHN: No. This is a regression on the sample
18 Dr. Miller just explained.

19 Q Dr. Miller.

20 A Thank you.

21 What this chart shows is the value of the index of
22 association, that I obtained from the multiple regression
23 analysis which I applied to the sample of women whose ages
24 were from 35 to 59. There were 775 women in that category.

25 Q In the sample?

P1T 003959

1 A Yes.

2 Q Why did you pick that age category for these purposes?

3 A I actually did the regressions on all age categories for
4 which there was sufficient data. I picked this for the
5 purposes of illustration because it is my understanding that
6 that was the age of Mrs. Cipollone at the time she was
7 diagnosed. That is that category.

8 Q All right.

9 A Actually three multiple regression analysis were
10 performed. Let me explain to you the differences among
11 them. It is important that we note that.

12 In the first regression analysis, the one labeled
13 "all," we were interested in the relationship, statistical
14 association between whether or not the women got lung cancer
15 and all of the variables whose -- information was contained
16 in the American Cancer Society study.

17 When we did that analysis, we got an index of
18 association, describing how strong that relationship was, of
19 .414.

20 Remember that index lies between zero and 1 so the
21 association was neither very weak because this number isn't
22 close to zero, nor was it very strong because this number is
23 not very close to 1. It was somewhere in the middle, a
24 moderate association, if you will.

25 The next regression analysis was performed in

P1T 003960

1 exactly the same way, but we only used the variable that
2 described smoking. So what we are now looking at is not the
3 association linking everything we knew about these women to
4 lung cancer, but only the association linking their smoking
5 to lung cancer. This, of course, included women who didn't
6 smoke that we measured whether or not they smoked. That
7 information was on the questionnaire.

8 When we did that, we find the statistical
9 association between all of the smoking information that we
10 had, and whether or not the women got lung cancer could be
11 described by an index of association of .157, a number much
12 closer to zero than it is to 1.

13 Finally, we did a third regression in which we did
14 all the non-smoking information about these women, but we
15 did not use information about smoking, that is why this is
16 called non-smoking variables and we found an index of
17 association of .370, that is, the non-smoking information
18 had a higher statistical association to lung cancer than did
19 the smoking information. In fact, considerably higher.
20 Went from .157 to .370.

21 Now, if a statistician with his practiced eye
22 looked at the numbers he also observed something else. He
23 observes if you add these two indexes of association, you
24 get a number that is greater than .414. In fact, you get
25 .57.

P1T 003961

1 In other words, there seems to be more information
2 in the sum of smoking and non-smoking associations than
3 there really is in all the data.

4 How could that be?

5 That could only occur if these two sets of factors
6 carried with them information about the other. If they
7 weren't really separate from the statistical association
8 point of view.

9 In other words, one can think of it in the
10 following ways: One can say, yeah, these smoking variables
11 carry with them non-smoking information.

12 In fact, there is yet another way to look at the
13 same observation. We can ask, what is the difference
14 between the index of association when you use all the
15 information about these women and the index of association
16 when you use only non-smoking information.

17 You can see that that difference is only .044.
18 That is all that is left for any additional variables to
19 explain. And specifically that means that smoking after you
20 take into account all the non-smoking information about
21 these women, smoking can only explain .044 at most.

22 Remember, this is what is left for the world to
23 explain. Smoking is part of the remaining world, not the
24 whole thing. So, at most, smoking could have explained
25 .044.

P1T 003962

1 The fact that it looked like it explained .157,
2 therefore, must be due to the fact that when you know a
3 woman smokes you know she is different from women who don't
4 in other respects that don't have anything directly to do
5 with her smoking. So women who smoke are in some ways
6 different from those who do not smoke. That is the
7 statistical -- that is the interpretation that a
8 statistician -- at least this statistician draws out of that
9 result.

10 Q Now, Dr. Miller, did you also do this regression
11 analysis on samples with respect to other age groups of
12 women in the study?

13 A Yes. As I said a moment ago, I did it for all the age
14 groups for which there was sufficient data.

15 Q What were the results of those?

16 A Very similar to these. Numbers changed somewhat, but
17 the idea that this sum was greater than this number,
18 prevailed throughout, and the fact that this difference --
19 the most it could have been due to smoking alone was smaller
20 than the index of association that appeared to come from
21 smoking, that prevailed, and the fact that the index of
22 association for smoking was a lot smaller than the index of
23 association for non-smoking, that repeated in all of the
24 groups as well.

25 Q Dr. Miller, did you also do a multiple regression

P1T 003963

1 analysis on all of the women in that age group?

2 A All women in that group, yes.

3 Q Not just a sample?

4 A Yes.

5 Q Maybe we can set up the next chart on that.

6 A Okay.

7 MR. COHN: I didn't identify it your Honor, I am
8 sorry. This is Defendants' Joint Trial Exhibit 3039.

9 Q Dr. Miller, does that chart represent the results of
10 your multiple regression analysis with respect to all the
11 women in that age group?

12 A Yes.

13 Q How many women were included in that analysis?

14 A There were over 82,000, 8,595 women in the American
15 Cancer Society study whose ages were between 55 and 59 at
16 the initiation, at the time they first participated in the
17 study.

18 Q What were the results of your multiple regression
19 analysis with respect to all women?

20 A Well, they are depicted here. All were all of the
21 factors that describe these women. Smoking and non-smoking
22 factors together, the index of association took a nose dive,
23 it went all the way down to .01 a number very close to zero.

24 In other words, we have a group of women only a
25 very small fraction have lung cancer. It is very, very hard

P1T 003964

1 to describe any relationship between anything and lung
2 cancer. It is only when you take that sample that has quite
3 a few lung cancer women in it that these associations begin
4 to look big.

5 Again we did a regression using only the smoking
6 variables and the index of association went down to .004,
7 practically zero. And finally when you did only the
8 non-smoking variables, the index of association was .007.

9 So using all of that, not just the sample, not a
10 group of women who were where lung cancer was over
11 represented with respect to the way it really appears in the
12 population, we find very small indexes of association.

13 Q Dr. Miller, did you run multiple regression analysis on
14 other age groups with all the people involved, like you did
15 in the 55 to 59 year-old women?

16 A No. We only did it on this one age group.

17 Q Why didn't you do it on other age groups with respect to
18 everybody in that category?

19 A We had a total of almost 6,000 observations on 350
20 variables. It is an immense body of data and these take a
21 long time, very difficult to do. Never mind cost and time,
22 just getting computer time is difficult. When we dealt with
23 the totality of data we restricted ourselves to just this
24 age group.

25 Q But you did do the sample multiple regressions on the

P1T 003965

1 other age groups?

2 A Yes, sir. As I have already testified.

3 Q You testified those results were consistent with the
4 ones you got here?

5 A Yes, sir.

6 Q Dr. Miller, you testified that your analysis suggested
7 that the smoking variable carried with them or included some
8 non-smoking information?

9 A Correct.

10 Q And did you do some further analysis with respect to the
11 relationship between the smoking and non-smoking variables?

12 A I did.

13 Q And do you have charts to indicate what the results of
14 that was?

15 A There are a couple of charts to display the results of
16 that work.

17 MR. COHN: Your Honor, this is Defendants' Joint
18 Trial Exhibit 3040.

19 Q Dr. Miller, again, is this a result of your multiple
20 regression analysis on a sample of the 35 to 59 year old
21 women?

22 A Yes. This is exactly the same sample that was used in
23 the previous exhibit and the same age group that was used to
24 illustrate it in that previous exhibit.

25 Q And could you explain what these results show?

P1T 003966

1 A Yes. In this set of multiple regression analysis, our
2 purpose was not to try to describe the strength of the
3 statistical association between smoking and lung cancer or
4 non-smoking information and lung cancer, from that we
5 hypothesized that knowing that a woman smokes and knowing
6 something else it tells us something else about it. We
7 wanted to look at that idea further.

8 One way to do it is to see if somehow, if we know
9 the non-smoking information about a woman, can we then
10 relate that to whether or not she smoked.
11 or other aspects of her smoking behavior. We had a number
12 of variables that dealt with smoking.

13 In order to save a little time, we just put on the
14 exhibit two of them, but the results for the others were
15 similar.

16 What we did here, for example, was we asked whether
17 the non-smoking information about these women was associated
18 statistically with whether the respondent is occurring or
19 former smoker. In other words, did this woman smoke
20 regularly and we found a relatively high indicative -- a
21 number somewhere between zero and 1.432.

22 When we did it with another measure of smoking
23 behavior, namely the number of years the respondents smoked,
24 we got a slightly higher value .480.

25 In general, what we found was that we were able to

P1T 003967

1 associate the statistical analysis associated as measured by
2 index of association.

3 Smoking behavior with non-smoking information about
4 the women to a greater extent than it associated lung cancer
5 with any information about the women.

6 Q Now, Doctor, did you also do this multiple regression
7 analysis with respect to all the women in this age group?

8 A With all the women in this age group we did. We
9 repeated this beyond the sample to all the women.

10 Q Just as you had done with the index of association with
11 lung cancer?

12 A Yes.

13 MR. COHN: This is 3041, Defendants' Joint Trial
14 exhibit.

15 Q Dr. Miller, let me ask you if this is the exhibit that
16 reflects your multiple regression analysis with respect to
17 all the women in that age group?

18 A It is.

19 Q And the age group is 33 to 59?

20 A Correct.

21 Q Okay.

22 A Here we repeated the same analysis only now we used all
23 the data, instead of about 775 women we had data on about
24 82,000, if you recall. We showed you those numbers a moment
25 ago.

P1T 003968

1 We got -- remember when we had the total data in
2 this age group, and we were interested in the statistical
3 relationship between all of the variables and lung cancer.

4 Q Would it be helpful to hold that one up.

5 A I think perhaps I could state it. If you recall, the
6 index of association was .010, very, very small.

7 Now, when we try to ask what is the association
8 between non-smoking data on these women and whether or not
9 the woman ever smoked, we get an index of association that
10 is much larger than that, it is .222. And if you do it with
11 whether the number of years the respondents has smoked it's
12 .253.

13 We did it with about ten other smoke variables,
14 variables that describe smoking of these women and whether
15 or not they smoked and we got similar numbers.

16 This reinforced perhaps more than the sample did
17 because of the big difference between the .01 and these
18 numbers that the smoking carries with it non-smoking
19 information, because if I know whether a woman -- if I know
20 the makeup of that woman is measured by these variables, I
21 have some ability to associate that with her smoking
22 behavior.

23 Q Thank you, Doctor.

24 Now, as a statistician, how do you interpret the
25 results of multiple regression analysis?

P1T 003969

1 A First, I want to say I used a very large body of data
2 here. Contained almost 600,000 individuals or data point.

3 Q These were the women?

4 A Yes. Each data point represented a woman. Like the
5 little pink circles on the graphs I showed you earlier,
6 almost 600,000 of them. There were many thousands in just
7 the sample.

8 These data points contained information not about
9 one or two or three factors, but about many factors.

10 We started out with 350 variables that described
11 all of the information on the American Cancer Society
12 questionnaires and the follow-ups.

13 We used standard methods of statistical analysis.
14 Namely, multiple regression commonly used in a wide variety
15 of statistical applications, well reported in the literature
16 both as to the theory and as to the application.

17 So using this large data base, and using this
18 standard method of statistical analysis, we found the
19 followings:

20 First, we found that the statistical association
21 between smoking and lung cancer is far smaller than the
22 statistical association between non-smoking information and
23 lung cancer.

24 We then found that there is an even stronger
25 association between non-smoking information and the smoking

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1 behavior of women. Which strongly suggests that women who
2 smoke are different in many ways as measured by all these
3 factors from women who do not smoke.

4 We are able to conclude from this that using
5 something as simplistic as relative risk, which can only
6 measure the statistical association between two variables,
7 in this case, smoking and lung cancer, doesn't do the job.
8 It doesn't go far enough because it omits the influence of
9 all these other variables which are there in the real world
10 and which we must contend with.

11 The influence of these other variables and other
12 factors is ignored when all we do is look at the relative
13 risk associated with smoking.

14 I have to conclude from all of this, Mr. Cohn, that
15 if we are going to find the answer to the question --

16 Q Excuse me just a second.

17 MR. COHN: I think we ought to take a side bar a
18 moment.

19 (The following takes place at side bar.)

20 MR. COHN: I think Dr. Miller was getting into
21 conclusions, so I thought I better come over.

22 THE COURT: Appreciate it.

23 MR. COHN: I think the man is fully qualified. His
24 conclusions as a statistician, which is the way I would
25 start to question him, I tried to distinguish between his

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1 interpretations of the data and his conclusions but he
2 started to go past the question.

3 MR. EDELL: The question is going to be cause --

4 MR. COHN: No. What conclusions, as a
5 statistician, he draws from it.

6 MR. EDELL: I assume -- well, until we can decide
7 what causes cancer, blah, blah, blah, blah, blah.

8 MR. COHN: He will explain what the present body of
9 data, statistical data can do and its limitations.

10 THE COURT: I will permit him.

11 Is there an objection?

12 MR. EDELL: Present body of the literature dealing
13 with this study alone. Only this data.

14 MR. COHN: On this data and his knowledge of the
15 literature.

16 MR. EDELL: Now, he will become an expert on all
17 epidemiology?

18 MR. COHN: No.

19 THE COURT: Talking about literature on statistics?

20 MR. COHN: On epidemiology which is statistical
21 literature. He testified he's read the articles, he has
22 gotten now the one study assuming it has the most data of
23 all of them. He read the others but the others don't have
24 this kind of data.

25 THE COURT: He will give an opinion as to this

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1 study, isn't he now --

2 MR. CONN: But he is --

3 THE COURT: I will permit it but you are broadening
4 it and making it confusing.

5 MR. CONN: I will ask him what does he conclude
6 having done this analysis.

7 In 1967 he has to get this data to analyze it and
8 he didn't get it. When you read a study in the paper, you
9 see what the data is that is reported. He reads the papers,
10 finally gets this data, analyzes it, and it comes to certain
11 conclusions based on the analysis of the data which is the
12 best he can get. But included in that conclusion is the
13 other general reading of the literature. I will not make a
14 big deal of it.

15 THE COURT: If you are saying that his opinion --
16 about the opinion about which he is about to render an
17 opinion, go back. If he is about to render an opinion based
18 upon something other than his analysis of this data, and his
19 education and experience as a statistician, you better have
20 him set forth what it is.

21 MR. CONN: Let me put it this way: I had no
22 intention of asking him anything, having done this analysis,
23 what are your conclusions. He testified that he read other
24 stuff, he has that in mind but his basic conclusions will be
25 based on what he has done here but he can't divorce himself

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1 from the general knowledge. If you get my point.

2 THE COURT: No. Because I am saying if it's
3 general knowledge in the field as a statistician -- I
4 thought he was about to render an opinion as to the validity
5 of the conclusions drawn from the studies, is that right?

6 MR. COHN: He doesn't go into it drawn by other
7 people --

8 THE COURT: But he will draw his own conclusions of
9 this study?

10 MR. COHN: Based upon the analysis of the study but
11 his conclusion is broader than the study.

12 THE COURT: Ask him first about the study and if he
13 goes outside --

14 MR. COHN: Doesn't go outside. Let me try it
15 again.

16 There is an epidemiologist study say over of 500
17 people in which they have their smoking habits, practices,
18 whatever you call it, age, where they live and sex, and that
19 is the study that says see I have a statistical association
20 between smoking and lung cancer.

21 THE COURT: Do it differently. Tell me the
22 question you will ask rather than his answer.

23 MR. COHN: That is not his answer. The question is
24 having done this, what are your conclusions with respect
25 to -- that is what I was going to ask him. Having done

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1 this, you have given us your interpretations of the data.

2 THE COURT: Do you have an opinion as to what?

3 MR. COHN: Well, I was going to ask for his
4 conclusions based on this data.

5 THE COURT: That is an opinion.

6 MR. COHN: His opinion.

7 THE COURT: As to what?

8 MR. COHN: His opinion is going to be that the data
9 is inconsistent with the hypothesis that cigarette smoking
10 causes lung cancer. Given this enormous amount of data,
11 that is here, even accepting its limitations, he doesn't
12 think that epidemiology can go any further or much further.
13 and the answer will have to come from something somewhere
14 else, not from the statistical study or epidemiological
15 study.

16 MR. EDSELL: He is becoming an expert in
17 epidemiology.

18 MR. COHN: Statistical analysis. Not some magic.
19 Doctor Hanley -- Mr. Cochran on the Advisory Committee
20 doesn't have a Ph.D.

21 MR. EDSELL: Not in epidemiology. They had Dr.
22 Schuman.

23 THE COURT: Let us not talk about anybody else.

24 The question is whether this is an expert and
25 whether he can give an opinion on the subject. I will

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1 certainly let him give, particularly based upon the analysis
2 he has done, his opinion as to this study and what
3 conclusions can be drawn. If he wants to go outside, tell
4 me what he is relying on before you ask an opinion.

5 Let us adjourn for lunch.

6 MR. COHN: Basically he will rely on this. As I
7 was saying, this is the only study with this kind of data.

8 THE COURT: No problem.

9 MR. SIRRIDGE: He indicated in his background he
10 was familiar with the literature in this area.

11 THE COURT: He hasn't said whether or not he is
12 relying upon it and if he is, I want to know what it is.

13 Let us adjourn for lunch.

14 (End of sidebar.)

15 THE COURT: We will adjourn for lunch and resume at
16 2:15.

17 THE CLERK: All rise.

18 (A luncheon recess was taken.)
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